

Exhibit 9-6

IN THE CIRCUIT COURT OF SHELBY COUNTY, TENNESSEE
FOR THE THIRTIETH JUDICIAL DISTRICT AT MEMPHIS

ACUMENT GLOBAL
TECHNOLOGIES, INC.,

Plaintiff,

vs.

MALLINCKRODT ARD INC. *et al*,

Defendants.

Docket No. CT-2275-19

Division VII

FILED
OCT 28 2019

CIRCUIT COURT CLERK
BY [Signature] C.C.

ORDER ADMITTING LAURA SHORES, SONIA KUESTER PFAFFENROTH,
RYAN WATTS AND MATT WOLF *PRO HAC VICE*

In accordance with Tennessee Supreme Court Rule 19, and based upon the Motions of Defendant Mallinckrodt Ard Inc. and Defendant Mallinckrodt plc (collectively "Mallinckrodt"), for the *pro hac vice* admission of Laura Shores, Sonia Kuester Pfaffenroth, Ryan Watts and Matt Wolf and their Amended Affidavits in support of their respective motions, the motions for admission *pro hac vice* are well taken and the Court finds that they should be GRANTED.

IT IS, THEREFORE, ORDERED, ADJUDGED, AND DECREED that Laura Shores, Sonia Kuester Pfaffenroth, Ryan Watts and Matt Wolf are hereby admitted *pro hac vice*, to act as co-counsel for Mallinckrodt in this case.

Ordered this the 28 day of October, 2019.

[Signature]
HON. MARY L. WAGNER
CIRCUIT COURT JUDGE

APPROVED AS TO FORM:

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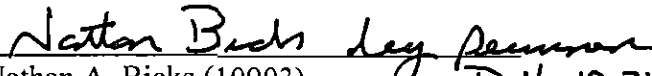
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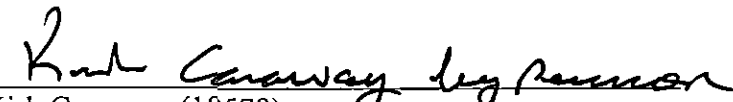
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CERTIFICATE OF SERVICE

I, Daniel W. Van Horn, attorney for Defendants, certify that a true and correct copy of the foregoing motion has been sent as follows:

via U.S. Mail, postage prepaid, this 22nd day of October 2019, to the following:

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Daniel W. Van Horn

**IN THE CIRCUIT COURT OF SHELBY COUNTY, TENNESSEE
FOR THE THIRTIETH JUDICIAL CIRCUIT AT MEMPHIS**

**ACUMENT GLOBAL TECHNOLOGIES,
INC.,**

Plaintiff,

v.

EXPRESS SCRIPTS ARD, INC., *et al.*,

Defendants.

DOCKET NO. CT-2275-19

JURY TRIAL DEMANDED

**PLAINTIFF’S SUR-REPLY IN FURTHER OPPOSITION TO
THE EXPRESS SCRIPTS DEFENDANTS’ MOTION TO DISMISS**

Plaintiff Acument Global Technologies, Inc. (“Plaintiff” or “Acument”), by and through its undersigned counsel, hereby submits this sur-reply in further opposition to the Express Scripts Defendants’ (collectively, “Express Scripts”)¹ Motion to Dismiss. This pleading is filed pursuant to the leave of Court ordered at the October 30, 2019 hearing on the Defendants’ Motions to Dismiss, in order to respond to the new arguments raised for the first time by Express Scripts in its Reply Brief.

PRELIMINARY STATEMENT

Express Scripts raised for the first time in its Reply Brief the issue of the potential applicability of a defense of statute of limitations to its pending dismissal arguments. In its opening Brief, filed July 23, 2019, Express Scripts raised only four (4) arguments for dismissal: (1) lack of antitrust standing and failure to allege anticompetitive conduct under the TTPA (as to

¹ The Express Scripts Defendants consist of the following, subsidiary business entities, all of which comprise Express Scripts: Express Scripts Holding Company; Express Scripts, Inc.; CuraScript, Inc., Priority Healthcare Corp. and Priority Healthcare Distribution, Inc., d/b/a CuraScript SD, Accredo Health Group, Inc., and United BioSource Corporation.

Counts I and II); (2) anticompetitive conduct is not actionable under the TCPA (as to Count III); (3) lack of particularity of fraud pleading (as to Count V); and (4) failure to plead unjust enrichment and conspiracy (as to Counts IV and VI). *See* Mem. of Law in Support of The Express Scripts Defendants’ Motion to Dismiss at 2-3. Nowhere did Express Scripts argue that any of Plaintiff’s claims were allegedly time barred under applicable statutes of limitations. Indeed, nowhere did Express Scripts point out to the Court any of the operative statutes of limitations that apply to Plaintiff’s claims.

Instead, realizing the insufficiency of their principal arguments in favor of dismissal, Express Scripts sought to interject two entirely new arguments for the first time in both its Reply Brief and at the hearing on the Motion to Dismiss. This was improper. The statute of limitations is an affirmative defense which must be timely raised in a pre-answer motion to dismiss. Tenn.R. Civ.P. 8.03; *Allgood v. Gateway Health Sys.*, 309 S.W.3d 918, 925 (Tenn. Ct. App. 2009)(“[A]n affirmative defense ... must be presented in the defendant’s answer or in a pre-answer motion.”). “The failure to comply with this rule will result in waiver of the defense[.]” *Allen v. Ozment*, 2018 Tenn. App. LEXIS 677 at *9 (Sept. 12, 2018)(citing Tenn.R.Civ.P. 12.08 (“A party waives all defenses and objections which the party does not present ... by motion”)).²

Because Express Scripts failed to comply with the Rules, instead choosing to surprise Plaintiff and this Court in its Reply Brief and at the hearing, Plaintiff counsel asked the Court to

² Equally important is the fact that Express Scripts was required by Rule to plead its defense of the alleged bar of the statutes of limitations with particularity in its Motion to Dismiss, but failed to do so. *See George v. Bldg. Materials Corp. of Am.*, 44 S.W.3d 481, 486 (Tenn. 2001)(An affirmative defense must be “specifically pleaded”); *Pratcher v. Methodist Healthcare Memphis Hospitals*, 407 S.W. 3d 727, 736 (Tenn. 2013)(“Rule 8.03 clearly contains a ‘specificity requirement.’ Rule 8.03 requires that a party ‘set forth affirmatively facts in short and plain terms relied upon to constitute ... [a] statute of repose [or statute of limitations]’ defense. ‘Conclusory allegations’ do not satisfy the specificity requirements of Rule 8.03.”)(citations omitted)(brackets in original).

strike the new arguments raised in the Express Scripts Reply Brief.³ The Court denied Plaintiff's request to strike, granting Plaintiff leave to file the instant Sur-Reply Brief. Accordingly, this Sur-Reply addresses the following new arguments raised by Express Scripts.

Statutes of limitations as a potential bar to Plaintiff's claims.

In its Reply Brief, and again at the hearing on their Motion, Express Scripts argued for the first time that the defense of the statute of limitations should bar all of Plaintiff's claims. Express Scripts Reply Br. at 14-17. For the first time, Express Scripts sought to set out the applicable statutes of limitations for each of Plaintiff's claims. *Id.* at 15 (arguing that "one-year and three-year statute of limitations [are] applicable" to Plaintiff's claims). Express Scripts further argued that Plaintiff's causes of action allegedly "accrued" on one of three possible dates, July 2, 2007, "in 2011", and/or in December 2015. *Id.* at 14-17. To avoid the fact that Acument sued Express Scripts in Rockford on December 8, 2017, Express Scripts argued that there should be no "cross-jurisdictional tolling", and the "continuing violation doctrine" should not apply. *Id.* at 15-16.

For the reasons discussed below, none of these new arguments warrants dismissal of Plaintiff's claims at this juncture on grounds of the running of the statutes of limitations.

Express Scripts' conduct allegedly does not "substantially effect" Tennessee trade or commerce.

In addition, in its Reply Brief and at the hearing, Express Scripts argued for the first time that its alleged anticompetitive conduct did not "substantially effect" Tennessee trade or

³ As Plaintiff counsel argued to the Court, an independent basis for striking the arguments raised for the first time in the Reply Brief is the fact that "[a] reply brief is a response to the arguments" of the opposing party. "It is not a vehicle for raising new issues." *Owens v. Owens*, 241 S.W.3d 477, 499 (Tenn. Ct. App. 2007). "It would be fundamentally unfair to permit" a movant "to advance new arguments in the reply brief", as the opposing party "may not respond to a reply brief." *Employers Pension Plan v. Clayton*, 209 S.W.3d 584, 594 (Tenn. Ct. App. 2006).

commerce under the TTPA. Reply Br. at 10-12. In its opposition, Plaintiff pointed out that “Express Scripts concedes that the alleged anticompetitive conduct at issue affected Tennessee trade or commerce. So, this Court need not dwell on the issue.” Reply Br. at 12 (quoting Plaintiff Opp. Br. at 16 n.16). Plaintiff so argued due to the fact that Express Scripts raised no such argument in its moving papers.

Rather than concede that the point was waived for failure to interpose a timely argument thereon, in its Reply, Express Scripts argued, “[t]he Express Scripts Entities have not, and do not, concede the point.” *Id.* Express Scripts then argued, for the first time, that “Plaintiff has not plausibly alleged that the challenged conduct had a substantial effect on Tennessee trade or commerce, ***which is yet another reason*** why the Court should dismiss Plaintiff’s TTPA and TCPA claims.” *Id.* (emphasis supplied).

Express Scripts then sought to argue this *other reason* for dismissal at the hearing. In doing so, Express Scripts sought to interject inappropriate facts in the guise of argument, directly contrary to the allegations of Plaintiff’s Complaint, the public record, and Express Scripts’ own corporate designee’s deposition testimony.⁴

This Sur-Reply seeks to set the record straight on the lack of merit of Express Scripts’ new arguments about the “substantial effect” of the Defendants’ conduct, especially the newly-interposed factual claims about CuraScript SD.

⁴ While a transcript of the hearing is not yet available to Plaintiff, counsel’s notes of the hearing reflect Mr. Lytle arguing for the first time how he was “surprised to learn” that CuraScript SD was based in Memphis, Tennessee, as Plaintiff pled in the Complaint and argued in its opposition papers. He then affirmatively argued, the CuraScript SD subsidiary was not based in Memphis Tennessee; it was based only in Lake Mary, Florida.

ARGUMENT

Express Scripts’ belated arguments about the statute of limitations and “substantial effect” of Defendants’ conduct on Tennessee trade and commerce should have been stricken by the Court as inappropriately and untimely interposed. *See supra.* notes 2 and 3. However, because this Court allowed Plaintiff the opportunity to submit this Sur-Reply Brief, Plaintiff does so with this Sur-Reply (without waiver of its procedural objections).

1. The Applicable Statutes of Limitations Do Not Support Express Scripts’ Request for Dismissal With Prejudice.

Express Scripts’ new argument that the applicable statutes of limitations should be held to bar Plaintiff’s causes of action fails for multiple reasons.

First, since a defense of the statute of limitations must be pleaded and proven by the defendant, it is generally not appropriate to grant a defense Motion to Dismiss on grounds of an affirmative defense. “The reliance on an affirmative defense in granting a motion to dismiss is very seldom sustainable.” *Ind. State Dist. Council of Laborers v. Brukardt*, 2009 Tenn. App. LEXIS 269 at *17-18 (Feb. 19, 2009). Our Supreme Court has admonished that, “when the affirmative defense relates primarily to an issue of fact”, as here, “different concerns may often counsel against deciding the merits of the affirmative defense in a motion to dismiss.” *Givens v. Mullikin*, 75 S.W.3d 383, 404 (Tenn. 2002). Such concerns include forcing a plaintiff to “anticipate matters that may be set up as affirmative defenses” in its pleading,⁵ and forcing courts to “resolv[e] a factual dispute only upon the complaint’s allegations [while] not fully

⁵ Compare *United States v. Carell*, 681 F.Supp. 2d 874, 877 (M.D.Tenn. 2009)(“Generally speaking, a 12(b)(6) motion to dismiss is not an appropriate vehicle for raising an affirmative defense, such as the statute of limitations, because plaintiffs are not required to ‘anticipate and attempt to plead around all potential defenses. Complaints need not contain any information about defenses and may not be dismissed for that omission.’”) (citations omitted).

consider[ing] whether other evidence exists that defeats or mitigates the apparent defense.” *Id.*

“[T]he more appropriate course of action in [such a] case is to permit the suit to continue so that the validity of these factual affirmative defenses may be tested by actual proof and not merely upon the potentially incomplete allegations of the complaint.” *Id.*

Second, the defense of the statute of limitations is a defense that must be pleaded **with specificity** by the defendant. *See George v. Bldg. Materials Corp. of Am.*, 44 S.W.3d at 486 (An affirmative defense must be “specifically pleaded”); *Pratcher*, 407 S.W. 3d at 736 (“Rule 8.03 clearly contains a ‘specificity requirement.’). “Rule 8.03 requires that a party ‘set forth affirmatively facts in short and plain terms relied upon to constitute ... [a] statute of limitations’ defense. Conclusory allegations’ do not satisfy the specificity requirements of Rule 8.03.” *Id.*

Express Scripts fails to satisfy this exacting standard in its Reply Brief. Instead, Express Scripts claims, in conclusory fashion only, as follows: “when one of Plaintiff’s beneficiaries received Acthar in 2011 pursuant to a ‘a direct relationship with the Express Scripts Defendants’, Plaintiff was on notice of its claims. At the very least, in December 2015, when Plaintiff paid CVS/Caremark \$68,186.75 per prescription of Acthar, it was on actual notice or else on inquiry notice.” Reply Br. at 16-17. Elsewhere, Express Scripts makes vague reference to the July 2, 2007 public announcement by Mallinckrodt about its new strategy for Acthar, without expressly arguing a factual basis for how or why this put Acument on notice of its claims. Reply Br. at 16.

Nowhere does Express Scripts explain, with specificity, what Plaintiff learned “in 2011” to put Plaintiff “on notice of its claims”, as required.⁶ Nowhere does Express Scripts explain

⁶ Indeed, Express Scripts has argued inconsistently elsewhere that there are no damages arising out of any of the 2011 conduct because Plaintiff “received no bill”, and therefore, according to Express Scripts, there would be no basis for any claim arising in 2011. *See, e.g.*, Reply Br. at 6 n. 4; Mem. of Law in Support of The Express Scripts Defendants’ Motion to Dismiss at 6

how or why “in December 2015” Plaintiff was put “on actual notice or else on inquiry notice of its claims.”⁷ Instead, Express Scripts simply cherry-picks these dates out of the Complaint because they are favorable to its arguments about the one and three year statutes of limitations.

Third, Express Scripts completely ignores the fact that Acument is part of the putative class in the *Rockford* action, and that therefore any statute of limitations applicable to its state law claims has been tolled since the filing of the *Rockford* class action on April 6, 2017. *See* ECF No. 1, 3:17-cv-50107 (N.D.Ill).⁸ Defendants have argued to this Court that Acument is part of the class in *Rockford*. *See, e.g.*, Mallinckrodt Motion to Dismiss at 1-2 (“Acument’s *Rockford* Action against these Defendants, which Acument joined in December 2017, was a sweeping putative class action on behalf of third party payors, just like Plaintiff, alleging federal and state antitrust claims, ... and a variety of state law claims.”)⁹ Thus, all statutes of limitations have been tolled in this case. *See China Agritech, Inc. v. Resh*, 138 S.Ct. 1800, 1806, 201 L.Ed. 2d 123, 2018 U.S. LEXIS 3502 (2018)(“*American Pipe* established that ‘the commencement of the original class suit tolls the running of the statute of limitations for all purported members of

(arguing “ESI served as Plaintiff’s PBM only *prior* to December 2015 – *ie., before* Plaintiff was charged for its beneficiary’s Acthar prescription”)(emphasis in original).

⁷ Express Scripts fails to account for the fact that Plaintiff continued to make inflated payments for Acthar well into December 2016, clearly rendering Plaintiff’s May 2019 Complaint filed in this Court well within the scope of the three-year statute of limitations for Acument’s statutory claims for most of its 2016 payments. Complaint ¶¶ 15-17, 25, 307-308.

⁸ Express Scripts’ arguments about “cross-jurisdictional tolling” completely miss the mark. Reply Br. at 15, n. 5. Acument does not require tolling under the cited Tennessee statute in view of binding United States Supreme Court precedent holding that Acument’s claims have been tolled by operation of the filed, pending class action in federal court.

⁹ The Court in the *Rockford* Action has ruled that the City of Rockford has standing to proceed as a putative class representative on behalf of classes for direct purchasers (like Rockford itself) and indirect purchasers (like Acument) of Acthar. *See generally, City of Rockford v. Mallinckrodt ARD, Inc.*, 360 F. Supp. 3d 730 (N.D. Ill. 2019).

the class who make timely motions to intervene after the court has found that the suit is inappropriate for class action status.”)(citation omitted); *see also*, *Crown v. Parker*, 462 U.S. 345, 354-55, 103 S.Ct. 2392, 76 L.Ed. 628 (1983)(“We conclude, as did the Court in *American Pipe*, that ‘the commencement of a class action suspends the applicable statute of limitations as to all asserted members of the class who would have been parties had the suit been permitted to continue as a class action.’”)(citation omitted).

Fourth, Express Scripts’ arguments about the “accrual” of Acument’s claims ignores the fact that the Complaint clearly alleges that Acument made inflated payments for Acthar **through December 2016**, rendering most of its claims from that year timely under the applicable three-year statute of limitations. *See supra*. n. 7. Since only the averments of Plaintiff’s Complaint are entitled to deemed true at this juncture, Express Scripts’ contrary arguments, and failure to plead with the requisite particularity, warrants denial of its Motion to Dismiss on grounds that Plaintiff’s claims accrued in December 2015.

Finally, Express Scripts argues that “Plaintiff cannot avail itself of the continuing action doctrine to toll the statute of limitations.” Reply Br. at 17. Again, Acument does not require tolling under such doctrine, in light of binding United States Supreme Court precedent. *See* discussion above 7-8. Even so, the observations of one Missouri federal court (in an unreported, non-binding 2019 decision)¹⁰ about what the Tennessee Supreme Court might do as to the continuing action doctrine hardly warrants dismissal with prejudice of Acument’s claims at this juncture, especially in the face of the Tennessee Supreme Court’s clear statement of the

¹⁰ In citing *In re Pre-Filled Propane Tank Antitrust Litig.*, 2019 U.S. Dist. LEXIS 161304 (W.D.Mo. Aug. 21, 2019), Express Scripts ignores the fact that even the Missouri Court observed that the “Tennessee courts have recognized that this statute of limitations [for TTPA claims] may be subject to the discovery rule and the fraudulent concealment doctrine.” *Id.* at *50.

applicability of the doctrine over twenty years ago. *See Spicer v. Beaman Bottling Co.*, 937 S.W.2d 884, 889 (1996) (“After a review of the relevant case law, we find persuasive the rationale supporting the continuing violation doctrine and adopt it in Tennessee.”).

2. Defendants’ Alleged Conduct Has a “Substantial Effect” on Tennessee Trade or Commerce.

Express Scripts separately argued for the first time in its Reply Brief, and at the hearing, that Defendants’ alleged antitrust conduct did not “fall[] within the scope of the TTPA [] ‘substantial effects’ standard.” Reply Br. at 10. While Express Scripts notes that proper test is the “‘effect’ on Tennessee trade or commerce”, *id.*, it fails to apply such test, instead arguing about the connection between the antitrust conduct and Tennessee, not the effects of such conduct. *Id.* at 11 (“Courts considering allegations with far more connections to Tennessee have dismissed similar claims.”)

As initially reported in Plaintiff’s Response to the Express Scripts Defendants’ Motion to Dismiss, to state a claim under the Tennessee antitrust law, a plaintiff must allege anticompetitive conduct which affects Tennessee trade or commerce to a “substantial degree.” *Freeman Industries, LLC v. Eastman Chemical Co.*, 172 S.W.3d 512, 523 (Tenn. 2005). The Supreme Court in *Freeman* distinguished “conduct” from “effect,” stating that “[t]he focus under the substantial effects standard . . . is not on the anticompetitive conduct itself but on the effects of the conduct on Tennessee commerce.” *Id.* at 524. “[T]he test is pragmatic, turning upon the particular facts of the case The anticompetitive conduct, however, need not threaten the demise of Tennessee businesses or affect market prices to substantially affect intrastate commerce.” *Id.* at 523-24.¹¹

¹¹ While the *Freeman* court dismissed an indirect purchaser’s claims against a business with its

In its Reply, Express Scripts highlights only the narrow, out-of-state aspects of this case. *Id.* at 10 (noting the states of incorporation of certain parties). It then challenged the averments of the Complaint that “certain of the Express Scripts Entities have operations in Tennessee.” *Id.* (challenging Complaint ¶¶ 31-41). At the hearing, Attorney Lyttle did the same, explicitly denying that CuraScript SD and potentially other Express Scripts subsidiaries had Tennessee-based operations. *See supra.* n. 4.

While Plaintiff is not required to offer any evidence to support its factual averments in the Complaint in response to a Motion to Dismiss, and Acument certainly doesn’t seek to convert the defense Motions into ones for summary judgment, this Court should know that defense counsel’s factual assertions are directly contrary to the allegations of Plaintiff’s Complaint, the public record,¹² and Express Scripts’ own corporate designee’s deposition testimony at a recent deposition.¹³ This is all that should be required at this juncture to raise a material factual dispute as to whether the alleged conduct of Defendants had a “substantial effect” on Tennessee trade or

principal place of business in Tennessee, the plaintiff failed to allege that any sales of the relevant product took place in Tennessee, only that the defendant, located in Tennessee, had orchestrated the conspiracy from Tennessee. *Id.* at 523-24. In contrast, Acument alleges that both it, and its beneficiary, are located in Tennessee, along with Dr. Tumlin and the Express Scripts Defendants. As a result, substantial sales of Acthar took place in Tennessee, warranting the application of Tennessee antitrust laws to the conduct at issue. In so alleging, Acument’s claims fall squarely within the ambit of the TTPA. *See, e.g., In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. 143, 166 (E.D.Pa. 2009)(finding “the amended complaint contains facts that ‘raise a reasonable expectation that discovery will reveal evidence of’ a substantial effect on the Tennessee economy sufficient to prove a claim under that state’s antitrust law.”)

¹² While the Court could simply take a drive down Century Parkway here in Memphis, and personally observe CuraScript’s local presence here, CuraScript SD’s public website includes a map of its distribution centers, listing Memphis as one of four locations. Another is listed address is Lake Mary, Florida, which defense counsel pointed out at the hearing. *See* <https://curascriptsd.com/specialty-distribution-group-purchasing>

¹³ Excerpt of Transcript of June 13, 2019 Deposition of United BioSource at 15-17 (confirming four locations of UBC)(at Exhibit “A” hereto).

commerce.

CONCLUSION

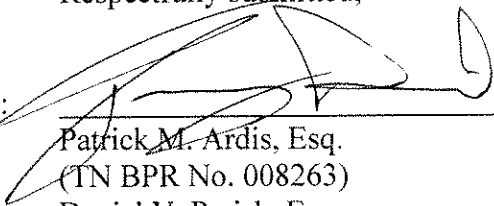
For the foregoing reasons, and those stated in Plaintiff's prior opposition papers and at the hearing on Defendants' Motions to Dismiss, the Express Scripts' Motion to Dismiss should be denied.

Dated: _____

11/13/19

Respectfully submitted,

By: _____


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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing has been delivered via U.S. mail and electronic mail this 13th day of November, 2019.

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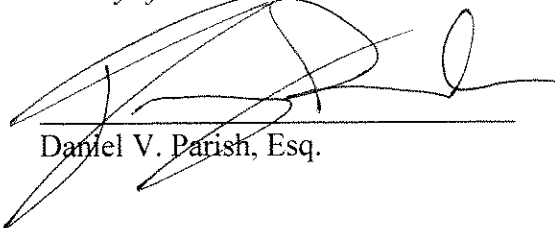
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Daniel V. Parish, Esq.

EXHIBIT A

IN THE COURT OF COMMON PLEAS
FOR MONTGOMERY COUNTY, PENNSYLVANIA
CIVIL ACTION NO. 2018-14059

- - - - -
INTERNATIONAL UNION OF
OPERATING ENGINEERS LOCAL
542,

Plaintiff,

vs.

VIDEOTAPED
DEPOSITION OF:
NICOLE HEBBERT

MALLINCKRODT ARD, INC.,
formally known as QUESTCOR
PHARMACEUTICALS, INC.;
MALLINCKRODT PLC; EXPRESS
SCRIPTS HOLDING COMPANY;
EXPRESS SCRIPTS, INC.;
CURAScript, INC., doing
business as CURAScript, SD;
ACCREDITO HEALTH GROUP, INC.,
and UNITED BIOSOURCE
CORPORATION,

June 13, 2019
9:04 a.m.

Defendants.

CONFIDENTIAL

BEFORE CHRISTINE STANCO, a Certified
Court Reporter, Certification Number XI000789, and
Notary Public, held at the MONTGOMERY COUNTY COURT
OF COMMON PLEAS, 2 East Airy Street, Norristown,
Pennsylvania, 19404, on Thursday, June 13, 2019,
commencing at 9:04 in the forenoon, pursuant to
notice.

JOSEPH ALBANESE & ASSOCIATES, INC.
Certified Court Reporters
250 Washington Street
Suite A
Toms River, New Jersey 08753
(732) 244-6100

Direct - Hebbert - Haviland

15

1 A. Yes.

2 Q. Okay. Because the distribution
3 side is taking product and then distributing it out
4 without doing clinical evaluation; is that fair?

5 A. Fair.

6 MR. MARTINO: Object to form.

7 BY MR. HAVILAND:

8 Q. Okay. You've been on the pharmacy
9 side?

10 A. Correct.

11 Q. Got it. And then in 2014, you
12 left that role?

13 A. Correct.

14 Q. At that time, it was Accredo?

15 A. Yes.

16 Q. Okay. To come to UBC?

17 A. Yes.

18 Q. Always in Florida?

19 A. I've never relocated.

20 Q. Okay. So UBC in Florida -- well,
21 let me ask this way. Where is UBC, is does it have
22 a headquarter?

23 A. Headquartered in Blue Bell,
24 Pennsylvania.

25 Q. So yours is an operating office?

Direct - Hebbert - Haviland

16

1 A. Correct.

2 Q. Okay. And what happens between
3 Blue Bell and, is it, Lake Mary?

4 A. Lake Mary.

5 Q. Okay. I'm just trying to
6 understand functionally, and there's another
7 location in Memphis?

8 A. I'm responsible at UBC for four
9 locations.

10 Q. Okay. I got Blue Bell, I got Lake
11 Mary, Florida?

12 A. Memphis, Tennessee; Overland Park,
13 Kansas; St. Louis, Missouri.

14 Q. Okay.

15 A. Did I get them all? Memphis, St. Louis,
16 Overland Park, Lake Mary.

17 Q. The headquarters in Blue Bell
18 oversees those four other operations around the
19 country?

20 A. Yes.

21 Q. Can you tell me functionally how
22 that works in terms of who's doing what?

23 A. So I am responsible for our patient
24 access services at UBC which is about half of the
25 organization. My operating locations are the ones

Direct - Hebbert - Haviland

17

1 we talked about, and we provide patient support
2 services through those various locations and
3 remotely with clinicians, reimbursement specialists
4 and various skill sets to support patients across
5 the country.

6 As it relates to Blue Bell, our
7 corporate functions are held in Blue Bell. So
8 legal, finance, HR, and then some IT and operating
9 functions are operated out of Blue Bell as well.

10 Q. What's the other half of the
11 organization? You said patient service was half?

12 A. Sure.

13 Q. Yes.

14 A. So the other half is our late stage
15 business, which is really supporting the drug
16 development process. So if you're familiar with
17 CRO, clinical research organizations --

18 Q. Sure.

19 A. -- working on safety profiles and
20 supporting drug development. So just think about
21 the FDA approval date, they work toward the
22 approval. I work on services after the approval.

23 Q. Got it. Okay. Is it fair to say
24 since 2014, you've always been on the patient side
25 services side?

**IN THE CIRCUIT COURT OF SHELBY COUNTY, TENNESSEE
FOR THE THIRTIETH JUDICIAL CIRCUIT AT MEMPHIS**

**ACUMENT GLOBAL TECHNOLOGIES,
INC.,**

Plaintiff,

v.

MALLINCKRODT ARD, INC., *et al.*,

Defendants.

DOCKET NO. CT-2275-19

DIVISION:

JURY TRIAL DEMANDED

**PLAINTIFF’S SUR-REPLY IN FURTHER OPPOSITION TO
THE MALLINCKRODT DEFENDANTS’ MOTION TO DISMISS**

Plaintiff Acument Global Technologies, Inc. (“Plaintiff” or “Acument”), by and through its undersigned counsel, hereby submits this sur-reply in further opposition to the Mallinckrodt’s¹ Motion to Dismiss. This pleading is filed pursuant to the leave of Court ordered at the October 30, 2019 hearing on the Defendants’ Motions to Dismiss, in order to respond to the new collateral estoppel argument raised for the first time by Mallinckrodt in its Reply Brief.

PRELIMINARY STATEMENT

Mallinckrodt raised for the first time in its Reply Brief the issue of the potential applicability of an affirmative defense of “collateral estoppel” to its pending dismissal arguments. In its opening Brief, filed July 29, 2019, Mallinckrodt raised only one overarching argument that Plaintiff’s Complaint allegedly fails to state a claim. *See* Mallinckrodt’s Mem. of Law and Authorities in Support of Motion to Dismiss Complaint Pursuant to Tennessee Rules 12.02(1) and 12.02(6), at 3. Like its counterpart Express Script, Mallinckrodt also raised

¹ “Mallinckrodt” consists of both Mallinckrodt ARD, Inc. and Mallinckrodt PLC.

secondary arguments for dismissal of Plaintiff's TTPA claims (Counts I and II), including an alleged lack of antitrust standing, and failure to allege a relevant market or monopoly power. However, nowhere did Mallinckrodt argue that Plaintiff's entire case should be barred under the doctrine of collateral estoppel. Indeed, nowhere did Mallinckrodt claim any "estoppel" let alone did Mallinckrodt cite to the Court the any relevant case law on collateral estoppel.

Instead, realizing the insufficiency of its principal arguments in favor of dismissal, Mallinckrodt jettisoned its main arguments for dismissal in favor of a late-asserted estoppel argument. In fact, collateral estoppel became the leading argument in the Mallinckrodt Reply and at the hearing. *See* Reply Br. at 3-5. This was improper.

Estoppel is an affirmative defense which must be timely raised in a pre-answer motion to dismiss. Tenn.R. Civ.P. 8.03; *Allgood v. Gateway Health Sys.*, 309 S.W.3d 918, 925 (Tenn. Ct. App. 2009)("[A]n affirmative defense ... must be presented in the defendant's answer or in a pre-answer motion."). "The failure to comply with this rule will result in waiver of the defense[]." *Allen v. Ozment*, 2018 Tenn. App. LEXIS 677 at *9 (Sept. 12, 2018)(citing Tenn.R.Civ.P. 12.08 ("A party waives all defenses and objections which the party does not present ... by motion"))).²

Because Mallinckrodt failed to comply with the Rules, instead choosing to surprise Plaintiff and this Court in its Reply Brief and at the hearing, Plaintiff counsel asked the Court to

² Equally important is the fact that Mallinckrodt was required by Rule to plead its affirmative defense of collateral estoppels with particularity in its Motion to Dismiss, but failed to do so. *See George v. Bldg. Materials Corp. of Am.*, 44 S.W.3d 481, 486 (Tenn. 2001)(An affirmative defense must be "specifically pleaded"); *Pratcher v. Methodist Healthcare Memphis Hospitals*, 407 S.W. 3d 727, 736 (Tenn. 2013)("Rule 8.03 clearly contains a 'specificity requirement.' Rule 8.03 requires that a party 'set forth affirmatively facts in short and plain terms relied upon to constitute ... [an affirmative] defense. 'Conclusory allegations' do not satisfy the specificity requirements of Rule 8.03.") (citations omitted)(brackets in original).

strike the new arguments raised in the Mallinckrodt Reply Brief.³ The Court denied Plaintiff's request to strike, granting Plaintiff leave to file the instant Sur-Reply Brief. Accordingly, this Sur-Reply addresses the following new estoppel argument raised by Mallinckrodt.

ARGUMENT

Mallinckrodt's belated arguments about collateral estoppel should have been stricken by the Court as inappropriately and untimely interposed. However, because this Court allowed Plaintiff the opportunity to submit this Sur-Reply Brief, Plaintiff does so with this Sur-Reply (without waiver of its procedural objections).

There are at least three (3) reasons why Mallinckrodt's belated request to have this Court apply principles of collateral estoppel should be denied at this juncture.

First, since a defense of collateral estoppel must be pleaded and proven by the defendant, it is generally not appropriate to grant a defense Motion to Dismiss on grounds of an affirmative defense. "The reliance on an affirmative defense in granting a motion to dismiss is very seldom sustainable." *Ind. State Dist. Council of Laborers v. Brukardt*, 2009 Tenn. App. LEXIS 269 at *17-18 (Feb. 19, 2009). Our Supreme Court has admonished that, "when the affirmative defense relates primarily to an issue of fact", as here, "different concerns may often counsel against deciding the merits of the affirmative defense in a motion to dismiss." *Givens v. Mullikin*, 75 S.W.3d 383, 404 (Tenn. 2002). Such concerns include forcing a plaintiff to "anticipate matters

³ As Plaintiff counsel argued to the Court, an independent basis for striking the arguments raised for the first time in the Reply Brief is the fact that "[a] reply brief is a response to the arguments" of the opposing party. "It is not a vehicle for raising new issues." *Owens v. Owens*, 241 S.W.3d 477, 499 (Tenn. Ct. App. 2007). "It would be fundamentally unfair to permit" a movant "to advance new arguments in the reply brief", as the opposing party "may not respond to a reply brief." *Employers Pension Plan v. Clayton*, 209 S.W.3d 584, 594 (Tenn. Ct. App. 2006).

that may be set up as affirmative defenses” in its pleading,⁴ and forcing courts to “resolv[e] a factual dispute only upon the complaint’s allegations [while] not fully consider[ing] whether other evidence exists that defeats or mitigates the apparent defense.” *Id.* “[T]he more appropriate course of action in [such a] case is to permit the suit to continue so that the validity of these factual affirmative defenses may be tested by actual proof and not merely upon the potentially incomplete allegations of the complaint.” *Id.*

Second, the defense of collateral estoppel is a defense that must be pleaded **with specificity** by the defendant. *See George v. Bldg. Materials Corp. of Am.*, 44 S.W.3d at 486 (An affirmative defense must be “specifically pleaded”); *Pratcher*, 407 S.W. 3d at 736 (“Rule 8.03 clearly contains a ‘specificity requirement.’). “Rule 8.03 requires that a party ‘set forth affirmatively facts in short and plain terms relied upon to constitute ... [an affirmative] defense. Conclusory allegations’ do not satisfy the specificity requirements of Rule 8.03.” *Id.*

Mallinckrodt fails to satisfy this exacting standard in its Reply Brief. Instead, Mallinckrodt argues broadly, based on one, unreported Tennessee appellate decision, that “[c]ollateral estoppel prohibits re-litigating issues that already have been fully and fairly litigated.” Reply Br. at 3 (*quoting Partin v. Scott*, No. E2007-02604-COA-R3-CV, 2008 Tenn. App. LEXIS 656 (Tenn. Ct. App. Nov. 13, 2008)). Nowhere does it explain how the “issues” **in this case** were “fully and fairly litigated” in the Rockford case. It does not do so, because it cannot do so.

In Tennessee, “[t]he party seeking to rely on the doctrine of collateral estoppel has the

⁴ Compare *United States v. Carell*, 681 F.Supp. 2d 874, 877 (M.D.Tenn. 2009)(“Generally speaking, a 12(b)(6) motion to dismiss is not an appropriate vehicle for raising an affirmative defense, such as the statute of limitations, because plaintiffs are not required to ‘anticipate and attempt to plead around all potential defenses. Complaints need not contain any information about defenses and may not be dismissed for that omission.’”) (citations omitted).

burden of proof.” *Dickerson v. Godfrey*, 825 S.W.2d 692, 695 (Tenn. 1992); *State v. Scarborough*, 181 S.W.3d 650, 655 (Tenn. 2005). To prevail with a collateral estoppel claim, the party asserting it must demonstrate:

- (1) that the issue sought to be precluded is identical to the issue decided in the earlier suit;
- (2) that the issue sought to be precluded was actually litigated and decided on its merits in the earlier suit;
- (3) that the judgment in the earlier suit has become final;
- (4) that the party against whom collateral estoppel is asserted was a party or is in privity with a party to the earlier suit; and
- (5) that the party against whom collateral estoppel is asserted had a full and fair opportunity in the earlier suit to litigate the issue now sought to be precluded.

Gibson v. Trant, 58 S.W.3d 103, 118 (Tenn. 2001)(citing *Beaty v. McGraw*, 15 S.W.3d 819, 824-25 (Tenn. Ct. App. 1998). “Moreover, in order for the doctrine of collateral estoppels to apply, the issue must not only have been actually litigated and decided, it must also have been necessary to the judgment.” *Mullins v. State*, 294 S.W.3d 529, 535 (Tenn. 2009).

Here, Mallinckrodt has pleaded none of the prerequisites for the application of collateral estoppel, much less with the requisite particularity for such an affirmative defense to be considered at the motion to dismiss stage. Instead, it pays lip service to the requirement that the issues for which estoppel is sought must have been actually “presented and decided in a prior action between the same parties.” Reply Br. at 5 (*quoting Deutsch v. Flannery*, 823 F.2d 1361, 1364 (9th Cir. 1987)(citing *Allen v. McMurry*, 449 U.S. 90, 94 (1980)). Mallinckrodt argues, contrary to the express elements set forth in the *Gibson* case, that it does not matter to application

of collateral estoppel that a prior dismissal of the case was without prejudice. *Id.* Ironically, the case Mallinckrodt relies for such proposition held *against* Mallinckrodt's position here.⁵

Mallinckrodt concedes that the parties and issues in this case are different from Rockford. For instance, Mallinckrodt concedes that Dr. Tumlin was not sued in Rockford, only in this case. As a result, the parties are not the same here as in Rockford. In turn, the claims against such parties are not the same. As a result, there could have been no "full and fair litigation" of such non-overlapping claims and issues.

In addition, as Plaintiff has pointed out, Plaintiff's Complaint here includes facts and legal theories that were not part of the Rockford case. In particular, new facts were alleged concerning Defendants' conduct in providing kickbacks to doctors in form of speaking fees and to patients in the form of patient assistance, which facts only arose with the unsealing of the *qui tam* action in Philadelphia this past summer. Like other plaintiffs in the country, Acument has asserted claims based on these new facts in support of its TCPA and common law claims that were nowhere pled in Rockford. Indeed, as Plaintiff's also pointed out, Defendants withdrew their Motions to Transfer a truly overlapping case filed by Acument's counsel on behalf of a union fund in Philadelphia to the Rockford court, thereby impliedly conceding the lack overlap between the two federal litigations. Accordingly, as there is no way the Rockford Court could have "fully and fairly litigated" the issues surrounding these newly revealed *qui tam* claims, or the Acument claims premised thereon, collateral estoppel may not apply.

⁵ In *Duetsch*, the Court of Appeals for the Ninth Circuit reversed the trial court's dismissal of an amended complaint on grounds that collateral estoppel did not apply where the amended complaint cured prior deficiencies in the plaintiff's pleading. 823 F.2d at 1365 ("The present complaint's statement of each claim is different enough to render the doctrine of issue preclusion inapplicable.")

Third, even if Mallinckrodt had sought to explain how this case is seeking to “re-litigate” the issues within the meaning of the collateral estoppel doctrine, such argument should fail based on the uncontroverted facts of record and the lack of legal authority to support Mallinckrodt’s position.

As Mallinckrodt concedes, Acument took a voluntary dismissal as of right under Federal Rule 41(a). By definition, there was no adjudication of the “issues”, let alone a “full and fair” adjudication. To the contrary, the Court in Rockford dismissed Acument’s claims, without prejudice and with express leave to re-plead. *City of Rockford v. Mallinckrodt ARD, Inc.*, 360 F. Supp. 3d 730, 753 (N.D. Ill. 2019). In other words, the Rockford Court anticipated future litigation of the issues, which did not occur due to Acument’s voluntary dismissal as of right. Thus, the first and only “full and fair litigation” of Acument’s claims and issues will occur in this Court, rendering collateral estoppel wholly inapplicable.

Mallinckrodt cites no legal precedent for its proposition that collateral estoppel may be applied to dismiss a plaintiff’s claims, with prejudice, where such claims were re-filed in state court after a Rule 41(a) voluntary dismissal was taken, following a Rule 12(b)(6) dismissal without prejudice and with express leave to re-plead. No such precedent exists. As in the case of the Defendants’ request that this Court be the first Tennessee state court in the thirty-six (36) years since *AGC* was decided to adopt the *AGC* Court’s standing rules for antitrust claims brought under the TTPA, so too Mallinckrodt asks this Court to be the first in the country to adopt an unprecedented, expansive view of the doctrine of collateral estoppels to preclude Acument’s full and fair litigation of its claims.

CONCLUSION

For the foregoing reasons, and those stated in Plaintiff's prior opposition papers and at the hearing on Defendants' Motions to Dismiss, the Mallinckrodt Motion to Dismiss should be denied.

Dated: 11/13/19

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing has been delivered via U.S. mail and electronic mail this 13th day of November, 2019.

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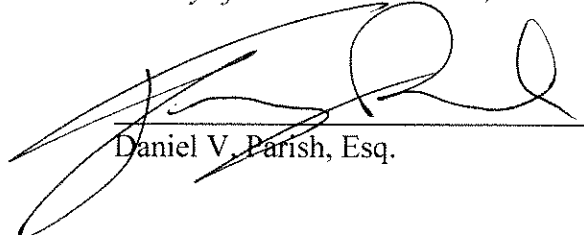
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IN THE CIRCUIT COURT OF SHELBY COUNTY, TENNESSEE
FOR THE THIRTIETH JUDICIAL CIRCUIT AT MEMPHIS

FILED

NOV 22 2019

CIRCUIT COURT CLERK
BY  D.C.

ACUMENT GLOBAL TECHNOLOGIES, INC.

Plaintiff,

v.

MALLINCKRODT ARD, INC., et al.,

Defendants.

Docket No. CT-2275-19

**THE EXPRESS SCRIPTS ENTITIES' MOTION FOR LEAVE TO FILE A RESPONSE
TO PLAINTIFF'S SURREPLY IN FURTHER SUPPORT OF THE EXPRESS SCRIPTS
ENTITIES' MOTION TO DISMISS**

Defendants Express Scripts Holding Co. ("ESHC"), Express Scripts, Inc. ("ESI"), CuraScript, Inc. ("CuraScript"), Priority Healthcare Corp., Priority Healthcare Distribution, Inc. d/b/a CuraScript SD ("CuraScript SD"), Accredo Health Group, Inc. ("Accredo"), and United BioSource Corp. ("UBC") (collectively, the "Express Scripts Entities") respectfully request leave of the Court to file a short response to Plaintiff's Surreply of no more than five (5) pages, attached hereto as Exhibit A, to correct certain misstatements of law raised in Plaintiff's Surreply concerning the applicable statutes of limitations and Tennessee's "substantial effects" test.

No delay will be caused by the Court granting this Motion, as the Express Scripts' Entities proposed response is attached directly hereto.

WHEREFORE, the Express Scripts Entities respectfully request that the Court grant their Motion for Leave and grant such other and further relief as the Court deems appropriate under the circumstances of this case.

Dated: November 22, 2019

Respectfully Submitted,



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Corp.***

CERTIFICATE OF CONSULTATION

I certify that Lani Lester, counsel for the Express Scripts Defendants, did consult with Don Haviland, counsel for the Plaintiff, via email on Tuesday, November 19, 2019, regarding the relief sought herein. Plaintiff opposes the motion.

A handwritten signature in black ink, appearing to read "E. C. Lyttle", written over a horizontal line.

Eric C. Lyttle

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I hereby certify that on November 22, 2019, a true and correct copy of the foregoing was sent by email or U.S. mail to the following:

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IN THE CIRCUIT COURT OF SHELBY COUNTY, TENNESSEE
FOR THE THIRTIETH JUDICIAL CIRCUIT AT MEMPHIS

FILED

NOV 22 2019

ACUMENT GLOBAL TECHNOLOGIES, INC.

CIRCUIT COURT CLERK
BY  D.C.

Plaintiff,

v.

Docket No. CT-2275-19

MALLINCKRODT ARD, INC., et al.,

Defendants.

**THE EXPRESS SCRIPTS ENTITIES' RESPONSE TO PLAINTIFF'S SURREPLY IN
FURTHER SUPPORT OF THE EXPRESS SCRIPTS ENTITIES' MOTION TO DISMISS**

Defendants Express Scripts Holding Co. ("ESHC"), Express Scripts, Inc. ("ESI"), CuraScript, Inc. ("CuraScript"), Priority Healthcare Corp., Priority Healthcare Distribution, Inc. d/b/a CuraScript SD ("CuraScript SD"), Accredo Health Group, Inc. ("Accredo"), and United BioSource Corp. ("UBC") (collectively, the "Express Scripts Entities") respectfully submit this short response to Plaintiff's Surreply. Plaintiff raises multiple arguments in its Surreply, none of which are supported by Tennessee state law.

First, Plaintiff rehashes the Court's ruling denying Plaintiff's motion to strike the arguments in the Express Scripts Entities' Reply related to the statute of limitations defense and the "substantial effects" test. Pl.'s Surreply at 1-4. In questioning the propriety of the Court's holding, Plaintiff ignores that it is "well settled" under Tennessee state law that a Court will not find a waiver of a statute of limitations defense "if the opposing party is given fair notice of the defense and an opportunity to rebut it." *George v. Bldg. Materials Corp. of Am.*, 44 S.W.3d 481, 487 (Tenn. 2001). Here, the Court granted Plaintiff leave to file a surreply, which courts have held is a proper exercise of a court's discretion that defeats a claim of waiver. *See, e.g., Cedars-Sinai Med. Center v. Shalala*, 177 F.3d 1126, 1128-29 (9th Cir. 1999) (holding that a statute of limitations defense raised for the first time in a reply to an opposition to a motion to dismiss was

not waived because plaintiffs were able to file a surreply addressing the issue); *Ben-Kotel v. Howard Univ.*, 319 F.3d 532, 536 (D.C. Cir. 2003) (stating that a court has discretion to allow the opposing party to file a surreply so the court may consider arguments contained in the reply); *Beaird v. Seagate Tech., Inc.*, 145 F.3d 1159, 1164 (10th Cir. 1998) (same).

Second, Plaintiff contends, pursuant to the U.S. Supreme Court's holdings in *American Pipe & Construction Co. v. Utah*, 414 U.S. 538 (1974), and *Crown, Cork & Seal Co., Inc. v. Parker*, 462 U.S. 345 (1983), that the statutes of limitations applicable to Plaintiff's Tennessee state law claims were tolled by the filing of the *City of Rockford* putative class action in the U.S. District Court for the Northern District of Illinois. Pl.'s Surreply at 7–8. That is incorrect. The Tennessee Supreme Court has explicitly rejected the tolling doctrine announced in *American Pipe* and *Crown*—and hence, precluded Plaintiff's argument here—given that it “would essentially grant to federal courts the power to decide when Tennessee's statute of limitations begins to run.” *Maestas v. Sofamor Danek Grp., Inc.*, 33 S.W.3d 805, 809 (Tenn. 2000); *see also In re Aredia & Zometa Prod. Liab. Litig.*, 754 F. Supp. 2d 939, 941 (M.D. Tenn. 2010) (holding that under *Maestas*, the “purported class action filed in federal court does not toll the state statute of limitations in Tennessee”); *In re Urethane Antitrust Litig.*, 663 F. Supp. 2d 1067, 1081 (D. Kan. 2009) (“Because Tennessee does not permit its statutes of limitations to be tolled by a class action filing in federal court, plaintiffs may not invoke the tolling doctrine in this case with respect to their claims under Tennessee law.”).

Third, Plaintiff argues that its causes of action first accrued in **December 2016**—the last time Plaintiff allegedly paid for Acthar. Pl.'s Surreply at 8. As an initial matter, Plaintiff has conceded that its TCPA and conspiracy claims are time barred under Tennessee's one-year statute of limitations for those claims; Plaintiff did not file its Complaint until May 2019, **more than two**

years after Plaintiff's chosen date of December 2016. For this reason, Plaintiff's TCPA (Count III) and conspiracy (Count VI) claims are not timely and must be dismissed.

Furthermore, no court in Tennessee has ever recognized the continuing violation doctrine as a means of tolling a statute of limitations for the type of claims that Plaintiff brings here, where an action is based on specific and repeated purchases of a product. Express Scripts Entities' Reply at 17 (citing *In re Pre-Filled Propane Tank Antitrust Litig.*, 2019 WL 4796528, at *15 (W.D. Mo. Aug. 21, 2019) (surveying Tennessee state case law)). *Spicer v. Beaman Bottling Co.*, 937 S.W.2d 884 (1996)—the only case Plaintiff cites in support of its assertion that Tennessee law provides for the tolling that Plaintiff seeks—concerns a similarly-titled but unrelated doctrine under the Tennessee Human Rights Act that allows Title VII plaintiffs to challenge ongoing, continuous discriminatory acts so long as one of those acts falls within the limitations period. That doctrine has no bearing on this case. Plaintiff therefore cannot toll the statute of limitations with respect to its claims that began to run—at the very latest—in **December 2015**, when it allegedly first paid CVS/Caremark \$68,186.75 for a single prescription of Acthar for one of its members. Express Scripts Entities' Reply at 16–17; *see* Compl. ¶¶ 24–25. Because Plaintiff did not file its Complaint until **May 2019**, its claims fall outside the relevant three-year and one-year statutes of limitations and therefore must be dismissed. Express Scripts' Entities Reply at 15–17.

Fourth, Plaintiff claims that the Express Scripts Entities did not plead its statute of limitations defense with specificity, and further that it would not be appropriate for the Court to decide the statute of limitations issue at the motion to dismiss stage. Pl.'s Surreply at 5–7. However, where—as here—the allegations in the complaint taken as true plainly demonstrate that a plaintiff's claims are untimely, dismissal of the complaint is wholly appropriate. Express Scripts Entities' Reply at 14 (citing *Schmank v. Sonic Auto., Inc.*, 2008 WL 2078076, at *3 (Tenn. Ct.

App. May 16, 2008)). Indeed, “Tennessee case law is replete with cases dismissed in the trial court based on the statute of limitations defense raised in a Rule 12.02 motion to dismiss.” *George v. Alexander Auto., LLC*, 2007 WL 2726373 (Tenn. Ct. App. Sept. 19, 2007).

Further, contrary to Plaintiff’s contention, the Express Scripts Entities in fact pleaded affirmative facts in support of their statute of limitations defense, specifically: (1) Plaintiff alleges that on July 2, 2007, Mallinckrodt publicly announced that it was limiting the distribution of Acthar to “just Express Scripts,” Compl. ¶ 60; (2) Plaintiff alleges that this exclusive distribution agreement allowed “Mallinckrodt to raise the prices of Acthar to exorbitant, non-competitive levels,” *id.* ¶ 13; and (3) beginning in December 2015, Plaintiff paid “the inflated price for Acthar” of \$68,816.75 per prescription for its beneficiary, *id.* ¶ 25. See Express Scripts Entities’ Reply at 16–17. This is all that Rule 8.03 requires. *Young ex rel. Young v. Kennedy*, 429 S.W.3d 536, 552–53 (Tenn. Ct. App. 2013) (“Rule 8.03 merely requires that the defendant set forth the facts supporting the [statute of limitations] defense ‘affirmatively’ . . . [N]othing in Rule 8.03 requires that these facts come from outside the Complaint.”). Plaintiff’s Complaint contains allegations that, taken as true, support a finding that by **December 2015**, Plaintiff began paying CVS/Caremark \$68,816.75 per prescription of Acthar. See Compl. ¶ 319. At that moment in time, Plaintiff knew of—or at least had gained “information sufficient to alert a reasonable person of the need to investigate,” *Sherrill v. Souder*, 325 S.W.3d 584, 593 n.7 (Tenn. 2010)—the claims it now brings for having allegedly “paid the artificially inflated prices” of Acthar. Because Plaintiff knew, or a reasonable person should have known, of its injury in December 2015, the claims it brings in its May 2019 Complaint are time barred. Express Scripts Entities’ Reply at 16–17.

Finally, Plaintiff argues that its claims are properly within the scope of the TTPA and TCPA because the Express Scripts Entities’ alleged conduct had a “substantial effect” on

Tennessee trade or commerce given that “substantial sales of Acthar took place in Tennessee.” Pl.’s Surreply at 9–10. This is precisely the type of conclusory allegation that countless courts have found insufficient to bring a party’s claims within the scope of the TTPA and TCPA. Express Scripts Entities’ Reply at 11–12 (citing cases). What Plaintiff in fact pleads is that it paid for Acthar for a **single member** located in Tennessee. Compl. ¶¶ 319–20. There are no allegations anywhere in the 406-paragraph Complaint to support Plaintiff’s conclusion proffered in its Surreply that “substantial sales of Acthar took place in Tennessee,” let alone that the Express Scripts Entities’ alleged conduct affected Tennessee trade or commerce to a substantial degree. Instead, Plaintiff attempts to divert from this glaring deficiency by raising a dispute about the location of CuraScript’s operations—which is an irrelevant question that directly contradicts the Tennessee Supreme Court’s directive that the location of a business in Tennessee is not what matters for the “substantial effects” inquiry; rather, it is the alleged anticompetitive conduct’s effects on Tennessee trade or commerce. *See Freeman Indus., LLC v. Eastman Chem. Co.*, 172 S.W.3d 512, 523 (Tenn. 2005); Express Scripts Entities’ Reply at 10. Even if the location of CuraScript’s operations was germane—which it is not—counsel for the Express Scripts Entities did not “affirmatively argue” that CuraScript was “based only in Lake Mary, Florida.” *See* Pl.’s Surreply at 4 n.4. Instead, counsel stated that **the Complaint** alleges that CuraScript is an Indiana corporation with corporate offices located in Lake Mary, Florida. Hr’g Tr. 71:1-4; *see* Compl. ¶ 34. Plaintiff’s sole allegation that a single member received Acthar in Tennessee is not enough to bring its claims within the scope of the TTPA (Counts I and II) and TCPA (Count III), and those claims must be dismissed.

For the foregoing reasons, all claims against the Express Scripts Entities should be dismissed with prejudice.

Dated: November 22, 2019

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CERTIFICATE OF SERVICE

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**IN THE CIRCUIT COURT OF TENNESSEE FOR THE
THIRTIETH JUDICIAL DISTRICT**

ACUMENT GLOBAL TECHNOLOGIES, INC.

Plaintiff,

V.

MALLINCKRODT ARD, INC., *et al.*,

Defendants.

DOCKET NO. CT-2275-19

Division: VII

**DEFENDANTS MALLINCKRODT ARD INC. AND MALLINCKRODT PLC’S
MOTION FOR LEAVE TO FILE A RESPONSE TO PLAINTIFF’S SUR-REPLY IN
FURTHER SUPPORT OF MALLINCKRODT’S MOTION TO DISMISS**

Defendants Mallinckrodt ARD, Inc. and Mallinckrodt plc (collectively, “Mallinckrodt”) respectfully request leave of the Court to file a short response, attached hereto as Exhibit A, to correct certain misstatements of law raised in Plaintiff’s Sur-reply concerning collateral estoppel. The Motion will not cause any delay, as Mallinckrodt’s proposed response is attached to the Motion. Mallinckrodt has contacted Plaintiff and Plaintiff does not consent to this Motion.

WHEREFORE, Mallinckrodt respectfully requests that the Court grant its Motion for Leave and grant such other and further relief as the Court deems appropriate under the circumstances of this case.

Dated: November 22, 2019

Respectfully submitted,



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CERTIFICATE OF CONSULTATION

I hereby certify that Sonia Pfaffenroth, counsel for Mallinckrodt, did consult with Don Haviland, counsel for the Plaintiff, in-person, on Friday, November 22, 2019, regarding the relief sought herein. Plaintiff opposes the motion.

CERTIFICATE OF SERVICE

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Exhibit A

**IN THE CIRCUIT COURT OF TENNESSEE FOR THE
THIRTIETH JUDICIAL DISTRICT**

ACUMENT GLOBAL TECHNOLOGIES, INC.

Plaintiff,

v.

MALLINCKRODT ARD, INC., *et al.*,

Defendants.

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DOCKET NO. CT-2275-19

Division: VII

**DEFENDANTS MALLINCKRODT ARD INC. AND MALLINCKRODT PLC’S
RESPONSE TO PLAINTIFF’S SUR-REPLY IN FURTHER OPPOSITION TO
MALLINCKRODT’S MOTION TO DISMISS THE COMPLAINT**

Defendants Mallinckrodt ARD Inc. and Mallinckrodt plc (collectively, “Mallinckrodt”), respectfully submit this brief response to Plaintiff’s sur-reply to Mallinckrodt’s Motion to Dismiss.

PRELIMINARY STATEMENT

At the Court’s October 30, 2019 hearing on Defendants’ Motions to Dismiss, Plaintiff requested that the Court strike Mallinckrodt’s arguments regarding collateral estoppel. The Court instead granted Plaintiff the opportunity to file a response to Mallinckrodt’s collateral estoppel arguments. As a threshold issue, Plaintiff’s profession of “surprise” is unconvincing: Mallinckrodt’s opening brief repeatedly makes the point that the claims here were litigated and rejected by the federal court in *Rockford*. Indeed, the very first page asserts that Acument here “re-lodges claims and allegations that it previously attempted to bring in Federal Court in Rockford, Illinois, only to have those claims rejected and dismissed at the pleadings stage in their entirety earlier this year.” The second page points out that in *Rockford*, “virtually identical” claims based on a “virtually identical set of underlying factual allegations” were dismissed.

While the reply brief indeed uses the formal terminology to make the point, the argument is the same: Acument's claims have already been considered and rejected, and whether dismissed on collateral estoppel grounds or considered on the merits, the Complaint should be dismissed, this time with prejudice.

ARGUMENT

Plaintiff challenges the application of collateral estoppel on three grounds, which are addressed in turn.

A. Collateral Estoppel May Be Decided at the Motion to Dismiss Stage

First, Plaintiff claims that it is “generally not appropriate to grant a defense Motion to Dismiss on grounds of an affirmative defense.” Pl.’s Sur-reply at 3. In support of this argument, it cites *Givens v. Mullikin*, 75 S.W.3d 383 (Tenn. 2002). *Givens* does not involve collateral estoppel at all. There, as Plaintiffs’ sur-reply acknowledges, the Tennessee Supreme Court stated that deciding the merits of an affirmative defense in ruling on a motion to dismiss may be inappropriate “when the affirmative defense relates primarily to an issue of *fact*.” *Id.* at 404 (emphasis added). Collateral estoppel, however, is “a question of law.” *Bowen ex rel. Doe v. Arnold*, 502 S.W.3d 102, 106 (Tenn. 2016); *Mullins v. State*, 294 S.W.3d 529, 535 (Tenn. 2009) (same). Accordingly, Tennessee courts regularly consider the merits of a collateral estoppel defense at the motion to dismiss phase. *See, e.g., Cartwright v. Garner*, No. W2016-01424-COA-R3-CV, 2018 WL 4492742, at *5 (Tenn. Ct. App., Sept. 19, 2018) (noting that trial court granted motion to dismiss based on collateral estoppel, res judicata, and statute of limitations grounds); *Torres v. Bridgestone/Firestone N. American Tire LLC*, 498 S.W.3d 565, 570-72 (Tenn. Ct. App. 2016) (describing trial court’s rulings on collateral estoppel at motion to dismiss stage); *Carson v. Challenger Corp.*, No. W2006-00558-COA-R3-CV, 2007 WL 177575, at *2

(Tenn. Ct. App., Jan. 25, 2007) (question on appeal is “[w]hether the trial court committed reversible error by denying Challenger’s motion to dismiss under the doctrines of res judicata and collateral estoppel.”). It is entirely appropriate for this Court to address the merits of collateral estoppel in ruling on the Motion to Dismiss.

B. The Requirements for Invocation of Collateral Estoppel Are Satisfied

Second, Plaintiff insists that Mallinckrodt has failed to explain “how the ‘issues’ in this case were ‘fully and fairly litigated’ in the Rockford case.” Pl.’s Sur-reply at 4. Mallinckrodt’s briefs do this at length. They point out in considerable detail how the core factual allegations here are the same as those rejected in *Rockford*, identifying for the Court the minimal differences between the two complaints and explaining why they do not rectify the shortcomings identified by the court in *Rockford*. Mallinckrodt’s Mem. in Support of its Mot. to Dismiss at 1-2; Mallinckrodt’s Reply at 5-7, 10, 15 (comparing the allegations to those specifically rejected as insufficient in *Rockford*).¹ Mallinckrodt has demonstrated that the issues and allegations are identical and that they were actually litigated and decided on the merits.

Acument correctly states that the dismissal in *Rockford* was without prejudice. Mallinckrodt’s reply explains why this does not change the result; collateral estoppel has been held to require dismissal even where the earlier dismissal was without prejudice. As the Ninth Circuit Court of Appeals explained in *Deutsch v. Flannery*, 823 F.2d 1361, 1364 (9th Cir. 1987), “[i]t matters not that the prior action resulted in a dismissal without prejudice, so long as the determination being accorded preclusive effect was essential to the dismissal.” The court supported the application of collateral estoppel to issues where there were “no differences in the two complaints” or where “the differences obviously lack substantive significance.” *Id.* at 1364.

¹ A chart laying out those additional factual allegations claim by claim is attached as Exhibit 1.

But for two of the plaintiff's three asserted claims, the plaintiff alleged new facts that shored up deficiencies described in the previous court's dismissal, so the Ninth Circuit did not apply collateral estoppel. *Id.* That is not the case here. *See* Mallinckrodt's Mem. in Support of its Mot. to Dismiss at 1-2; Mallinckrodt's Reply at 5-7, 10, 15. The differences in the allegations are insignificant, and do not cure the deficiencies in the *Rockford* complaint—deficiencies that were “essential” to its dismissal.

The Eighth Circuit Court of Appeals also has barred relitigation of a case dismissed without prejudice. In *Germain Real Estate Co., LLC v. HCH Toyota, LLC*, 778 F.3d 692 (8th Cir. 2015), the court applied collateral estoppel to a case seeking to adjudicate issues related to the same agreements at issue in a previously dismissed case, despite differences in the alleged causes of action. *Id.* at 696. The court focused on the question of whether the state-court judgment “was sufficiently firm to be considered final for purposes of issue preclusion.” *Id.* In concluding that it was, it pointed to three facts: (1) the parties submitted briefs on the motion to dismiss in Arkansas state court; (2) the transcripts from the oral argument on the motion to dismiss “[made] clear that the parties were fully heard”; and (3) plaintiff could have appealed the dismissal without prejudice. *Id.* This case is no different.² Plaintiff could have amended its complaint in the Northern District of Illinois, but chose instead to withdraw it and refile it here, hoping for a different result. That is not allowed.

Plaintiff also argues that collateral estoppel does not apply because it named an additional defendant in this case and because the causes of action in this case are not precisely the same as those in *Rockford*. Pl.'s Opp. at 6. First, Tennessee law does not require mutuality for collateral

² Although there was no oral argument on the motion to dismiss in *Rockford*, Acument did not request an oral argument until a party in a case that was coordinated with *Rockford* made such a request. *See* Pls. City of Rockford & Acument Global Tech., Inc.'s Resp. to Pl. MSP Recovery Claims Series LLC's Request for Oral Arg., *City of Rockford v. Mallinckrodt*, No. 3:17-cv-50107 (May 9, 2018) ECF No. 143.

estoppel. *Bowen ex rel. Doe v. Arnold*, 502 S.W.3d 102, 115 (Tenn. 2016). Tennessee law only requires that the party against whom collateral estoppel is sought was a party in the previous proceeding. *Mullins v. State*, 294 S.W.3d 529, 535 (Tenn. 2009). Both Acument and Mallinckrodt were parties in *Rockford*, and both are parties in this case. Acument is estopped from pursuing claims against Mallinckrodt in this Court that were found patently deficient in *Rockford*. That an additional defendant has been brought into this case by Plaintiff is irrelevant. A plaintiff cannot escape the effect of collateral estoppel simply by adding an additional defendant. Second, collateral estoppel can apply “even when the claims or causes of action are different.” *Gibson v. Trant*, 58 S.W.3d 103, 113 (Tenn. 2001) (quoting *State ex rel. Cihlar v. Crawford*, 39 S.W.3d 172, 179 (Tenn. Ct. App. 2000)). The Complaint’s assertion of different claims, based on the same allegations, does not foreclose collateral estoppel.

C. Allegations Borrowed from the *Qui Tam* Case Are Deficient for Other Reasons

Finally, Plaintiff argues that the Complaint’s new allegations borrowed from a *qui tam* action that was unsealed after the ruling in *Rockford*, saves it from dismissal on collateral estoppel grounds. But Mallinckrodt has never asserted that Plaintiff is precluded from litigating those issues. In addition to their failure to remedy the deficiencies identified by the Rockford court, those allegations fail on their merits. The *qui tam* complaint concerns alleged promotion of Acthar to neurologists for off-label uses related to treatment of multiple sclerosis. This case, in contrast, alleges that Dr. Tumlin, a nephrologist, prescribed Acthar to Acument’s beneficiary for an FDA-approved indication—treatment of Idiopathic Membranous Nephropathy, a kidney disease. The substantial differences between the factual allegations in the *qui tam* complaint and in this case demonstrate the lack of significance of the *qui tam* allegations to this case.

CONCLUSION

For the reasons stated above and in Mallinckrodt's opening and reply briefs, the Court should dismiss the Complaint. Moreover, because Plaintiff had the opportunity to remedy the shortcomings in its complaint both in the *Rockford* proceeding and in this Court, and failed to do so, Mallinckrodt respectfully requests that the Court dismiss the Complaint in its entirety with prejudice.

Dated: November 22, 2019

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Exhibit 1

Counts I & II: Tennessee Trade Practices Act (Antitrust Standing)

Standard Under TN Law	“[A] plaintiff must demonstrate proximate cause between the alleged injury and the defendant’s injurious conduct” under the TTPA. <i>Perry v. American Tobacco Co., Inc.</i> , 324 F.3d 845, 851 (6th Cir. 2003).
Ruling in <i>Rockford</i>	<p>“Acument would not meet even the least stringent state’s ‘proximate cause’ test. . . . [T]he [Second Amended Complaint (“SAC”)] lacks sufficient allegations to allow the court to determine how Acument’s injuries in Tennessee are connected to defendants’ conduct.” <i>City of Rockford v. Mallinckrodt ARD, Inc.</i>, 360 F.Supp.3d 730, 760 (N.D. Ill. 2019).</p> <p>“Curiously, the SAC claims that payments for Acthar flow directly from Acument to CVS, which is described as one of the ‘co-conspirators,’ yet no details are provided anywhere else in the SAC as to how CVS participates in the alleged conspiracy.” <i>Id.</i> at 752, n.11 (internal citations omitted).</p> <p>“Thus, the court grants defendants’ motions to dismiss [plaintiffs’ claims alleging violations of state antitrust and consumer protection laws] as it pertains to Acument. The court grants plaintiffs leave to replead to correct the deficiencies associated with Acument’s ‘proper party’ status concerning its state-law claims.” <i>Id.</i> at 760.</p>
New Allegations in Complaint Relevant to Counts I & II (Antitrust Standing)¹	<u>Paragraphs 24-25, 306-312:</u> In 2011, when Dr. Tumlin first prescribed Acthar to Acument’s beneficiary, Express Scripts administered Acument’s prescription drug benefits. Acument received no bill and made no payment for the Acthar prescription in 2011. Dr. Tumlin again prescribed Acthar to Acument’s beneficiary in 2015-2016, and at that time, CVS/Caremark provided pharmacy benefit management services to Acument. Acthar paid CVS/Caremark for those prescriptions at a price of AWP minus 15.75%. CVS/Caremark then routed the payments to Express Scripts.
Implications of New Allegations	The new allegations do not reduce the attenuation between Acument’s payments and Mallinckrodt.

¹ This chart only includes those new allegations (1) relevant to the basis for the *Rockford* court’s dismissal of Acument’s complaint in *City of Rockford v. Mallinckrodt ARD, Inc.*, 360 F.Supp.3d 730 (N.D. Ill. 2019) and (2) specific to claims as to Mallinckrodt.

Counts I & II: Tennessee Trade Practices Act (Antitrust Injury)

Standard Under TN Law	Plaintiff must allege facts showing that it was “injured or damaged” by Mallinckrodt’s alleged anticompetitive conduct. Tenn. Code Ann. §47-25-106.
Ruling in <i>Rockford</i>	The <i>Rockford</i> court declined to analyze antitrust injury related to Acument’s TTPA claim because it dismissed the TTPA claim for lack of antitrust standing. <i>City of Rockford v. Mallinckrodt ARD, Inc.</i> , 360 F.Supp.3d 730, 760 (N.D. Ill. 2019).
New Allegations in Complaint Relevant to Counts I & II (Antitrust Injury)	<p><u>Paragraph 62:</u> Mallinckrodt and Express Scripts ended their exclusive distribution arrangement after the City of Rockford brought suit against them.</p> <p><u>Paragraphs 72-76:</u> Mallinckrodt’s pricing strategy begun in August 2007 was an “orphan drug strategy” based on the prediction that because Acthar was the only product indicated for IS, the market would absorb much higher prices for Acthar with little resistance.</p> <p><u>Paragraphs 118, 121, 124-125, 130, 136, 143-44:</u> Mallinckrodt sought Express Scripts’ approval before instituting price increases for Acthar, or at least notified Express Scripts prior to increasing the price of Acthar.</p> <p><u>Paragraph 264:</u> In a public statement released by Mallinckrodt on June 29, 2018, Mallinckrodt admitted that it did not pursue commercialization of Synacthen for IS and falsely claimed that the reason for not doing so was because it viewed the “barriers to completion” to be “virtually impossible to overcome.”</p>
Implications of New Allegations	None of the new allegations make it less speculative that absent Questcor’s acquisition of Synacthen, another bidder would have commercialized Synacthen, which would have caused the price of Acthar to decline prior to 2016 when Plaintiff alleges it last paid for Acthar. Nor do Plaintiff’s new allegations support the conclusion that if Mallinckrodt had used multiple distributors for Acthar, or had distributed Acthar directly, Acthar’s price would have been lower.

Count III: Tennessee Consumer Practices Act

Standard Under TN Law	<p>“In order to recover under the TCPA, the plaintiff must prove: (1) that the defendant engaged in an unfair or deceptive act or practice declared unlawful by the TCPA and (2) that the defendant’s conduct caused an ‘ascertainable loss of money or property, real, personal, or mixed, or any other article, commodity, or thing of value wherever situated.’” <i>Tucker v. Sierra Builders</i>, 180 S.W.3d 109, 115 (Tenn. Ct. App. 2005) (quoting Tenn. Code Ann. § 47-18-109(a)(1)).</p> <p>“Claims based on anticompetitive conduct are not cognizable under the TCPA.” <i>Sherwood v. Microsoft Corp.</i>, No. M2000-01850-COA-R9CV, 2003 WL 21780975, at *33 (Tenn. Ct. App. July 31, 2003).</p>
Ruling in Rockford	<p>Plaintiff did not allege a claim under the TCPA in <i>Rockford</i>, though because it brought claims on behalf of a purported class, it alleged violations of consumer protection statutes of other states.</p> <p>The <i>Rockford</i> court found that because “Acument would not meet even the least stringent state’s ‘proximate cause’ test,” Acument did not “sufficiently allege that Acument is a proper party to bring <u>any</u> antitrust or consumer protection claims (federal or state).” <i>City of Rockford v. Mallinckrodt ARD, Inc.</i>, 360 F.Supp.3d 730, 760-61 (N.D. Ill. 2019) (emphasis in original).</p>
New Allegations in Complaint Relevant to Count III (TCPA)	<p><u>Paragraphs 376a-c, 376f-h, 378-380</u>: In 2007, Mallinckrodt entered into an exclusive distribution agreement with Express Scripts that allowed Mallinckrodt to raise and fix the price of Acthar at supra-competitive levels, despite the drug’s lack of value, and to maintain monopoly power in the market for ACTH drugs.</p>
Implications of New Allegations	<p>As discussed in connection with Counts I & II, the new allegations do nothing to resolve the issue of attenuation between Acument’s payments for Acthar and money Mallinckrodt received for those prescriptions.</p> <p>The new allegations relate to alleged anticompetitive conduct, which is not actionable under the TCPA. To the extent that Plaintiff contends its TCPA claim relies on the new allegations of fraudulent or deceptive conduct, see the discussion relating to Counts V & VI below.</p>

Count IV: Unjust Enrichment

Standard Under TN Law	<p>“The elements of an unjust enrichment claim are: 1) ‘[a] benefit conferred upon the defendant by the plaintiff’; 2) ‘appreciation by the defendant of such benefit’; and 3) ‘acceptance of such benefit under such circumstances that it would be inequitable for him to retain the benefit without payment of the value thereof.’ <i>Freeman Indus. LLC v. Eastman Chem. Co.</i>, 172 S.W.3d 512, 525 (Tenn. 2005) (quoting <i>Paschall’s Inc. v. Dozier</i>, 407 S.W.2d 150, 155 (Tenn. 1966)).</p>
Ruling in Rockford	<p>“Assuming that Acument is in privity of contract with CVS, Acument does not allege that it has exhausted any remedies against CVS. This is fatal to Acument’s claim. The exhaustion requirement may be lifted if plaintiffs plausibly allege that such an effort would be ‘futile,’ but Acument has not done so.” <i>City of Rockford v. Mallinckrodt ARD, Inc.</i>, 360 F.Supp.3d 730, 772 (N.D. Ill. 2019).</p> <p>“[T]he court grants defendants’ motions to dismiss [plaintiff’s claim for unjust enrichment] without prejudice, and grants Acument leave to replead to correct the deficiencies noted here if it can do so consistent with the proper pleading requirements.” <i>Id.</i></p>
New Allegations in Complaint Relevant to Count IV (Unjust Enrichment)	<p><u>Paragraphs 383-84</u>: Acument made direct payments to CVS/Caremark that were transferred to Mallinckrodt through its exclusive agent, Express Scripts, pursuant to a prescription written by Dr. Tumlin. Acument was charged an inflated average wholesale price for the prescriptions of Acthar. All Defendants were unjustly enriched by the extremely high prices for Acthar.</p>
Implications of New Allegation	<p>None of the new allegations relate to either the exhaustion of Plaintiff’s remedies against CVS Caremark, the company to whom it made direct payments, or the futility of such an effort.</p>

Counts V & VI: Fraud and Conspiracy to Defraud

Standard Under TN Law	<p>A claim for fraud under Tennessee law requires a plaintiff to allege facts showing “(1) intentional misrepresentation of material fact; (2) knowledge that the representation was false—that the misrepresentation was made knowingly or recklessly or without belief or regard for its truth; (3) reasonable reliance on the misrepresentation by the plaintiff and resulting damages; and (4) that the misrepresentation relates to an existing or past fact[.]” <i>Dog House Inv., LLC v. Teal Prop., Inc.</i>, 448 S.W.3d 905, 916 (Tenn. Ct. App. 2014).</p> <p>“In all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity.” Tenn. R. Civ. P. 9.02.</p>
Ruling in Rockford	<p>“Plaintiffs’ [common law fraud] allegations in the SAC lack the requisite particularity imposed by the heightened pleading standard.” <i>City of Rockford v. Mallinckrodt ARD, Inc.</i>, 360 F.Supp.3d 730, 776 (N.D. Ill. 2019).</p> <p>As to the allegation that “defendants misrepresented that the price for Acthar represented the real and fact-based prices for their drugs . . . plaintiffs fail to sufficiently plead the factual information informing defendants of the ‘who, when, where, what, and how’ components of a valid fraud claim.”” <i>Id.</i></p> <p>“[U]nder Tennessee law, a ‘claim for civil conspiracy requires an underlying predicate tort allegedly committed pursuant to the conspiracy.’ Because plaintiffs have not met their pleading requirements under Rule 9(b) for alleging fraud, plaintiffs’ conspiracy to defraud claims must be dismissed as well.” <i>Id.</i> at 777 (internal citation omitted).</p>
New Allegations in Complaint Relevant to Counts V & VI (Fraud and Conspiracy to Defraud)	<p><u>Paragraphs 146-148, 151:</u> In a June 29, 2018 Mallinckrodt press release, Mallinckrodt’s CEO, Mark Trudeau, cited a price for Acthar that Mallinckrodt knew was false. In reality, private payors like Acument pay a higher price for Acthar than that cited by Mr. Trudeau.</p> <p><u>Paragraphs 152-155:</u> Government and private assistance programs use the average wholesale price (“AWP”) to determine prescription drug reimbursement and use the AWP listed in pharmaceutical industry publications, such as the Red Book and Medispan. Defendants “knew that they could, and did directly, control and raise the AWP for Acthar at any time simply by forwarding to the pricing compendia a new and higher AWP.”</p> <p><u>Paragraph 286-296, 299-305:</u> Mallinckrodt paid Dr. Tumlin to conduct non-FDA approved clinical studies to support the use of Acthar for nephrotic syndrome. Mallinckrodt provided Dr. Tumlin with Acthar at no charge to conduct the studies. Mallinckrodt then provided funding to Dr. Tumlin to travel around the country to cite</p>

	<p>data from his studies and promote the use of Acthar for nephrotic syndrome. Mallinckrodt paid Dr. Tumlin between fifteen and fifty thousand dollars per year from 2013-2016.</p> <p><u>Paragraphs 200-220:</u> In April 2019, a <i>qui tam</i> case was unsealed in federal court in Pennsylvania. The complaint in that case alleges that Mallinckrodt promoted Acthar for off-label use and provided kickbacks to doctors in the form of free Acthar as part of that promotion. It further alleges that Mallinckrodt paid bonuses tied to sales growth to sales representatives who promoted Acthar for off-label use.</p>
Implications of New Allegations	<p>The 2018 press release occurred more than two years after Plaintiff's last payment for Acument.</p> <p>The AWP allegations and the allegations regarding Dr. Tumlin do not allege with particularity—or otherwise—any misrepresentations by Mallinckrodt or any reliance by Plaintiff on any such misrepresentations.</p> <p>The allegations regarding the <i>qui tam</i> lawsuit relate to alleged off-label promotion of Acthar to neurologists for use in treatment of a neurological disease (MS). The patient in this case was allegedly prescribed Acthar for the treatment of Idiopathic Membranous Nephropathy (kidney disease).</p>

**IN THE CIRCUIT COURT OF SHELBY COUNTY, TENNESSEE
FOR THE THIRTIETH JUDICIAL CIRCUIT AT MEMPHIS**

**ACUMENT GLOBAL
TECHNOLOGIES, INC.**

Plaintiff,

v.

MALLINCKRODT ARD, INC., et al

Defendants.

DOCKET NO. CT-2275-19

DIVISION: VII

JURY TRIAL DEMANDED

MOTION TO WITHDRAW AS COUNSEL FOR PLAINTIFF

COMES NOW R. H. "Chip" Chockley (hereinafter referred to as "Counsel") and hereby files this Motion to Withdraw as co-counsel for the Plaintiff, Acument Global Technologies, Inc. in the above-styled case. In support of this Motion, the undersigned states as follows:

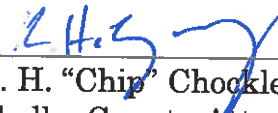
1. Counsel is no longer employed as an attorney with the law firm of Wolff Ardis, P.C. Counsel is now an Assistant County Attorney with the Shelby County Attorney's Office.
2. Daniel Parish and Patrick Ardis of Wolff Ardis, P.C., along with Donald E. Haviland, Jr. and William H. Platt, II of Haviland Hughes will continue to represent the Plaintiff in this matter.
3. The Plaintiff will not be prejudiced by the withdrawal of R. H. "Chip" Chockley, and his withdrawal will not result in any delay in this matter.

4. The Plaintiff has been advised and consents to the withdrawal of R. H. "Chip" Chockley.

5. Counsel would request that this Honorable Court enter an Order allowing Counsel to withdraw. Notice has been given to counsel for Defendants, who do not object to this Motion.

WHEREFORE, PREMISES CONSIDERED, R. H. "Chip" Chockley requests that he be allowed to withdraw as attorney of record and be relieved of any obligation to represent Acument Global Technologies, Inc. further in this matter.

Respectfully submitted,



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CERTIFICATE OF CONSULTATION

Undersigned counsel hereby certifies that Defendant's counsel, was consulted by email on November 25, 2019 with respect to the issues set forth in this Motion and counsel has no objection.



R. H. "Chip" Chockley

CERTIFICATE OF SERVICE

I do hereby certify that a copy of the foregoing has been sent via email, to the following on this the 26th day of November, 2019:

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Accredo Health Group, Inc. and United
BioSource Corp.*



R.H. "Chip" Chockley

**IN THE CIRCUIT COURT OF SHELBY COUNTY, TENNESSEE
FOR THE THIRTIETH JUDICIAL CIRCUIT AT MEMPHIS**

**ACUMENT GLOBAL TECHNOLOGIES,
INC.,**

Plaintiff,

v.

EXPRESS SCRIPTS ARD, INC., *et al.*,

Defendants.

DOCKET NO. CT-2275-19

DIVISION:

JURY TRIAL DEMANDED

**PLAINTIFF'S OMNIBUS OPPOSITION TO DEFENDANTS' MOTIONS FOR LEAVE
TO FILE RESPONSES TO PLAINTIFF'S SUR-REPLY**

Plaintiff Acument Global Technologies, Inc. ("Plaintiff" or "Acument"), by and through its undersigned counsel, hereby submits this omnibus brief in opposition to the Motions for Leave to File Responses to the Plaintiff's Sur-Reply Briefs in opposition to the Defendants' Motions to Dismiss. In the interest of brevity and completeness, Plaintiff files this one brief setting forth Plaintiff's opposition to afford the Court the opportunity to rule expeditiously on the two Motions for Leave filed by the Mallinckrodt¹ and Express Script Defendants.²

At the outset, Plaintiff timely objected at the start of the October 30, 2019 hearing to the attempt by both sets of the Defendants to interject new arguments in their respective Reply Briefs in support of their Motions to Dismiss Plaintiff's Complaint. Plaintiff moved to strike

¹ The Mallinckrodt Defendants consist of Mallinckrodt ARD, Inc. and Mallinckrodt plc.

² The Express Scripts Defendants consist of the following, subsidiary business entities, all of which comprise Express Scripts: Express Scripts Holding Company; Express Scripts, Inc.; CuraScript, Inc., Priority Healthcare Corp. and Priority Healthcare Distribution, Inc., d/b/a CuraScript SD, Accredo Health Group, Inc., and United BioSource Corporation.

those arguments as untimely and inappropriate.³ The Court denied the Motion to Strike, granting Plaintiff alone leave to file a Sur-Reply Brief to the defense arguments of (1) collateral estoppel (Mallinckrodt) and (2) statutes of limitations (Express Scripts). Plaintiff filed the Sur-Reply Briefs, as ordered, on November 13, 2019.

However, always seeking to get in the last word, both sets of Defendants have sought leave of Court to file yet *a third brief* in support of their Motions to Dismiss, styled a “Response to Plaintiff’s Sur-Reply”. The purported grounds for such Motions are to “correct misstatements of law” supposedly raised in Plaintiff’s Sur-Reply Briefs. Mallinckrodt Motion for Leave at 1; Express Scripts Motion for Leave at 1. However, neither brief is limited to making such purported “correction” in the law; instead, both third briefs seek to interject new cases and new arguments in support the belated defense arguments. Specifically, Mallinckrodt’s Third Brief seeks to add five (5) pages of argument, with eight (8) new case citations (not included in either Mallinckrodt’s Reply or Plaintiff’s Sur-Reply), and a lengthy, new chart (attached as Exhibit “1”) purporting to “lay[] out [the] additional factual allegations claim by claim.” Similarly, Express Scripts’ Third Brief seeks to add five (5) pages of argument, with ten (10) new case citations (not included in either Express Scripts’ Reply or Plaintiff’s Sur-Reply), and a brand new basis for its new statute of limitations argument – “by December 2015, ...[a]t that point in time, Plaintiff knew of ... the claims it now brings....” Express Scripts’ Third Brief at 4.

The unfair prejudice to Plaintiff is now compounded by this seemingly never-ending stream of argument by Defendants. In view of the Court’s query yesterday, through Mildred

³ “A reply brief is a response to the arguments” of the opposing party. “It is not a vehicle for raising new issues.” *Owens v. Owens*, 241 S.W.3d 4778, 499 (Tenn. Ct. App. 2007). “It would be fundamentally unfair to permit” a movant “to advance new arguments in the reply brief”, as the opposing party “may not respond to a reply brief.” *Employers Pension Plan v. Clayton*, 209 S.W.3d 584, 594 (Tenn. Ct. App. 2006).

Williams, Judicial Assistant for Circuit Court Judges, concerning the “finality” of the Rockford Court’s Order terminating Acument, it is imperative that either (1) the Defendants’ Motions for Leave to file their attached third briefs be denied, and the proffered briefs and legal and factual arguments interposed therein be stricken from the record, or (2) Plaintiff must be afforded the opportunity to rebut the erroneous legal and factual arguments interjected in the Defendants’ third briefs, by being granted leave to file a response to the third briefs, and by being given the opportunity to be heard at a subsequent hearing on these issues.⁴

⁴ For instance, Mallinckrodt now seeks to argue that this Court should treat the matter of collateral estoppel as a “question of law” and follow the decision of the Eight Circuit Court of Appeals in *Germain Real Estate Co., LLC v. HCH Toyota, LLC*, 778 F.3d 692 (8th Cir. 2015) in dismissing this case with prejudice due to the supposed finality of the Acument’s Rule 41(a) dismissal. Mallinckrodt Third Brief at 2-4. However, Mallinckrodt fails to point out that the non-binding decision of the Eight Circuit presented the inapposite (and in fact opposite) situation of a federal court looking to predict the law of a state court (Arkansas) on issue preclusion for purposes of applying federal full faith and credit to a final judgment in state court, not the federal law pertaining to a Rule 41(a) dismissal). 778 F.3d 695-96; *see also*, *Citibank, N.A. v. Data Lease Financial Corp.*, 904 F.2d 1498, 1501 (9th Cir. 1990)(“federal law defines the preclusive effect if a Rule 41(a) dismissal”). In contrast, federal law expressly holds that a Rule 41(a)(1) dismissal – as was done here by Acument, voluntarily and as of right – did not require a court order, despite the fact Judge Kapala chose to enter an Order terminating Acument after seeking any objections from Defendants. *See* Fed.R.Civ.Proc. 41(a)(1)(A)(“the plaintiff may dismiss an action without a court order by filing ... a notice of dismissal before the opposing party serves either an answer or a motion for summary judgment”). “If a defendant desires to prevent a plaintiff from voluntary dismissal under Rule 41(a)(1)(i), it may do so by merely filing an answer or motion for summary judgment. But, ‘so long as the defendant elects to abstain from the decisive joining of the issue’ by answer or motion for summary judgment, the plaintiff is still entitled to dismissal by notice as a matter of right.” *Merit Ins. Co. v. Leatherby Ins. Co.*, 581 F.2d 137, 143 (7th Cir. 1978)(citations omitted). A Rule 41(a) dismissal without prejudice is not a final order to which a subsequent court can apply principles of estoppel. *See, e.g., D.C. Elecs., Inc. v. Narton Corp.*, 511 F.2d 294, 298 (6th Cir. 1975)(“Rule 41(a)(1)(i) is clear and unambiguous on its face and admits of no exceptions that call for the exercise of judicial discretion by any court...”); *Marshall v. Kan. City S. Ry.*, 378 F.3d 495, 500 (5th Cir.)(“when a district court grants a party’s request for voluntary dismissal, he ‘gets what he seeks, i.e., a dismissal without an adjudication on the merits, and he is entitled to bring another suit on the same cause of action.’”); *Harrell v. Biomet Orthopedics, LLC*, 2015 U.S.Dist. LEXIS 179847 at *16-17 (W.D.Tenn. Feb. 25, 2015)(“Fed.R.Civ.P. 41(a) is ‘based on the consideration that when a voluntary dismissal is without prejudice[,] the plaintiff is placed in a legal position as if he had

CONCLUSION

For these reasons, the Defendants' Motions for Leave to File Responses to the Plaintiff's Sur-Reply Briefs in opposition to the Defendants' Motions to Dismiss should be denied. Alternatively, should the Court grant the Motions for Leave, Plaintiff should be afforded the opportunity to rebut the erroneous legal and factual arguments interjected in the Defendants' third briefs, by being granted leave to file a response to the third briefs, and by being given the opportunity to be heard at a subsequent hearing on these issues.

Dated: 11/26/19

Respectfully submitted,

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never brought the first suit and has the right to bring a later suit on the same cause of action without adjudication of the merits.”)(*quoting Dearth v. Mukasey*, 516 F.3d 413, 415 (6th Cir. 2008)); *Cf. Citibank*, 904 F.2d at 1501 (a stipulation under Rule 41(a)(1)(A)(ii) of “dismissal of a complaint **with prejudice** satisfies the requirement that there be a final judgment on the merits”)(emphasis supplied).

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing has been delivered via U.S. mail and electronic mail this 26th day of November, 2019.

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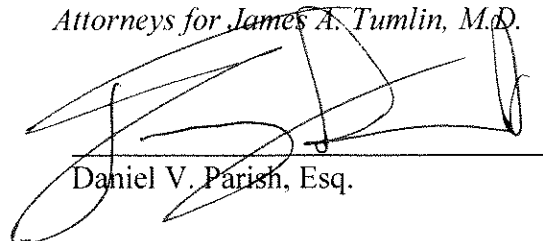
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IN THE CIRCUIT COURT OF SHELBY COUNTY, TENNESSEE
FOR THE THIRTIETH JUDICIAL CIRCUIT AT MEMPHIS

FILED
DEC 06 2019

ACUMENT GLOBAL
TECHNOLOGIES, INC.

Plaintiff,

v.

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Defendants.

CIRCUIT COURT CLERK
BY [Signature] D.C.

DOCKET NO. CT-2275-19

DIVISION: VII

JURY TRIAL DEMANDED

ORDER GRANTING MOTION TO WITHDRAW AS COUNSEL FOR
PLAINTIFF

This matter came before the Court upon the Motion to Withdraw of R. H. "Chip" Chockley filed in this cause. Upon agreement of the parties and for good cause shown,

IT IS HEREBY ORDERED, ADJUDGED AND DECREED that R. H. "Chip" Chockley's Motion to Withdraw shall be and is hereby granted, and that R. H. "Chip" Chockley shall hereby be relieved as counsel for Plaintiff.

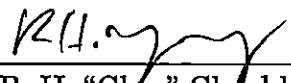
IT IS FURTHER ORDERED, ADJUDGED AND DECREED that Daniel Parish, Patrick M Ardis, and the law firm of Wolff Ardis, P.C. remain as counsel of record for the Plaintiff.

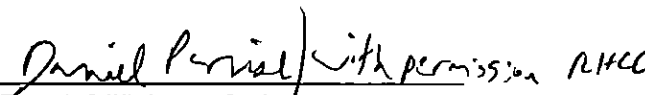
JUDGE

DATE:

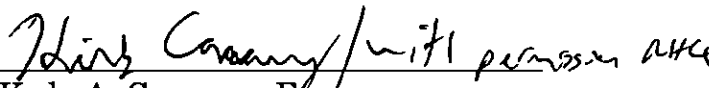
[Signature]
12/16/2019

APPROVED.


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R.H. "Chip" Chockley

IN THE CIRCUIT COURT OF SHELBY COUNTY, TENNESSEE
FOR THE THIRTIETH JUDICIAL CIRCUIT AT MEMPHIS

ACUMENT GLOBAL TECHNOLOGIES,
INC.,

Plaintiff,

v.

MALLINCKRODT ARD, INC., *et al.*,

Defendants.

DOCKET NO. CT-2275-19

DIVISION: VII

JURY TRIAL DEMANDED

**PLAINTIFF'S NOTICE OF SUPPLEMENTAL AUTHORITY IN SUPPORT
OF ITS RESPONSE TO DEFENDANTS' MOTION TO DISMISS**

Plaintiff, Acument Global Technologies, Inc. ("***Plaintiff***"), respectfully submits this Notice of Supplemental Authority in Support of its Response to the Defendants' respective Motions to Dismiss, and states as follows:

1. On July 29, 2019, Defendants Mallinckrodt ARD and Mallinckrodt plc ("***Mallinckrodt***") filed a Motion to Dismiss Plaintiff's Complaint. Plaintiff responded in opposition on October 16, 2019. Mallinckrodt filed their Reply on or about October 28, 2019.

2. Also on July 24, 2019, Defendants, Express Scripts Holding Company, Express Scripts, Inc., CuraScript, Inc., Curascript SD, Accredo Health Group, Inc., and United BioSource Corporation (hereinafter "***Express Scripts Entities***") filed their own Motion to Dismiss Plaintiff's Complaint. Plaintiff responded in opposition on October 16, 2019. The Express Scripts Entities filed their Reply on October 28, 2019.

3. Defendant Dr. James A. Tumlin, MD (“Tumlin”) filed his own Motion to Dismiss Plaintiff’s Complaint on August 15, 2019. Plaintiff responded in opposition on October 16, 2019. Tumlin filed his Reply on October 28, 2019.

4. Plaintiff’s Complaint asserted the following claims against Mallinckrodt, the Express Scripts Entities and Tumlin (collectively, the “Defendants”):

- a. Antitrust under the Tennessee Trade Practices Act (the “TTPA”) (Counts I and II);
- b. Monopolization and Price Fixing under the TTPA (Counts I and II);
- c. Relief under the Tennessee Consumer Protection Act (the “TCPA”) (Count III);
- d. Unjust Enrichment (Count IV);
- e. Fraud (Count V) and
- f. Conspiracy to Defraud (Count VI)

5. While the Defendants’ respective Motions to Dismiss are pending a ruling by this Court, both Mallinckrodt and the Express Scripts Entities sought dismissal of a similar case filed in the United States District Court for the Eastern District of Pennsylvania captioned *Steamfitters Local Union No. 420 v. Mallinckrodt ARD, LLC, et al.*, 2019cv3047 (The Honorable Berle M. Schiller). A copy of the Complaint is attached hereto as Exhibit “A”. A copy of the Defendants’ Motions to Dismiss are attached hereto as Exhibits “B” and “C”, respectively.

6. On December 19, 2019, in a one-page order, Judge Schiller denied the Defendants’ respective motions to dismiss claims similar to those filed in the case at bar, including claims asserted against Dr. Tumlin, a named defendant here.

7. While Tumlin is not named as a Defendant in the case before Judge Schiller, Judge Schiller considered and found merit to the facts alleged against Dr. Tumlin here (i.e., kickbacks paid by Defendants to doctors) in denying the Motions to Dismiss Plaintiff's consumer fraud claims.

8. Plaintiff respectfully requests that this Court accept Judge Schiller's Order as supplemental authority in ruling on the pending motions to dismiss. A copy of the December 19, 2019 Order is attached hereto as Exhibit "D".

Submitted this the 6th day of January, 2020.

Respectfully submitted,

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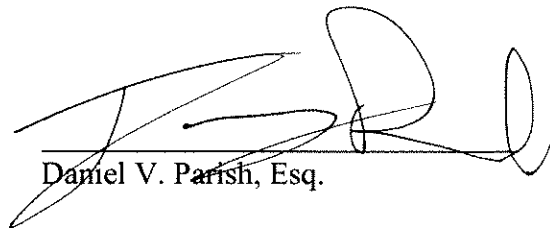
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STEAMFITTERS LOCAL UNION NO. 420,

individually and on behalf of all others

similarly situated,

14420 Townsend Road

Philadelphia, PA 19154

Plaintiff,

v.

MALLINCKRODT ARD, LLC,

f/k/a Mallinckrodt ARD, Inc.;

f/k/a Questcor Pharmaceuticals, Inc.;

1425 U.S. Route 206

Bedminster, NJ 07921

UNITED BIOSOURCE CORPORATION,

now known as UNITED BIOSOURCE LLC,

a wholly owned subsidiary of UNITED

BIOSOURCE HOLDINGS, INC.

920 Harvest Drive

Blue Bell, PA 19422

Defendants.

IN THE UNITED STATES DISTRICT
COURT FOR THE EASTERN
DISTRICT OF PENNSYLVANIA

CIVIL ACTION NO. _____

CIVIL CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

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CIVIL CLASS ACTION COMPLAINT

Plaintiff, Steamfitters Local Union No. 420 (***“Local 420” or “Plaintiff”***), by and through its undersigned counsel, individually and on behalf of all other third-party payors (“TPPs”) and their beneficiaries similarly situated, alleges as follows:

I. NATURE OF THE CASE

1. Steamfitters Local Union No. 420 brings this action on behalf of itself, its beneficiaries, and all other TPPs and their beneficiaries similarly situated, to challenge the unjust, unfair and deceptive marketing and sales scheme and conspiracy by Defendants, Mallinckrodt ARD LLC, formerly known as Mallinckrodt ARD, Inc., and, prior to that, formerly named Questcor Pharmaceuticals, Inc. (***“Questcor”***)(collectively ***“Mallinckrodt”***), along with its named and unnamed co-conspirators as further described herein. Specifically, Plaintiff names United BioSource Corporation n/k/a United BioSource LLC (***“UBC”***) for its direct role in the scheme and conspiracy alleged.

2. Mallinckrodt manufactures, markets, distributes and sells H.P. Acthar Gel, NDC Nos. 63004-8710-01 and 63004-7731-01 (***“Acthar”***). Acthar is the only therapeutic ACTH product sold in the United States. Mallinckrodt is the sole provider of Acthar in the U.S.

3. Mallinckrodt acquired Acthar in July 2001, when Questcor purchased Acthar from Aventis Pharmaceutical Products Inc. for \$100,000.

4. Acthar is a “specialty pharmaceutical”. Unlike most prescription drugs, it is not sold in retail pharmacies, nor is it distributed through wholesalers to retail pharmacies. Instead, it is distributed only through “specialty pharmacy distributors” (***“SPDs”***) and “specialty pharmacy providers” (***“SPPs”***).

5. While there are dozens of SPDs and SPPs in America, one of the largest SPDs is

CuraScript, Inc., doing business as CuraScript SD, and Priority Healthcare Corp, also doing business as CuraScript SD (collectively, “**CuraScript**”). One of the largest SPPs is Accredo Health Group, Inc. (“**Accredo**”). Express Scripts, Inc. has owned both CuraScript and Accredo since 2004. Express Scripts also owned UBC, and its predecessor entity HealthBridge, from 2007 through the end of 2017.

6. In 2007, Mallinckrodt decided to embark on a self-described “new strategy” with respect to the distribution, pricing, marketing and sales of Acthar. The mastermind of this new strategy was Gregg LaPointe, a member of Questcor’s Board of Directors at the time, who joined with Steve Cartt, Questcor’s Chief Operating Officer, to convince another Board member, Don Bailey, that the strategy should be implemented, over the objections of the existing Questcor CEO and several Board members and executives.

7. The new strategy had three essential components to it. These three components comprise the schemes that underscore the RICO enterprises and unfair and deceptive acts and practices at issue in this case.

8. First, Mallinckrodt changed the way it distributed and sold Acthar (the “**Distribution Scheme**”). It limited the distribution of Acthar from multiple distribution outlets to just one, CuraScript, and engaged UBC to act as its exclusive “HUB” of operations controlling both the distribution and reimbursement of Acthar directly with patients and TPPs. (CuraScript and UBC were both subsidiaries of Express Scripts.) Mallinckrodt created this exclusive distribution arrangement to limit and control distribution and output of Acthar, and to raise the prices of Acthar to unconscionable levels. Mallinckrodt and UBC created the Acthar Support and Access Program (“ASAP”) described below as the vehicle to effectuate their Distribution Scheme.

9. While this conduct constitutes antitrust, and is the subject of a separate federal class action lawsuit pending in Rockford, Illinois¹, it is also the subject of separate *qui tam* lawsuits brought in this Court by former employees of Mallinckrodt, in which the federal government has intervened. *See U.S. ex. Rel. Charles Strunck and Lisa Pratta v. Mallinckrodt ARD, Inc., et al.* 2:12-cv-00175-BMS (E.D.Pa.) at Document No. 40 (“*Strunck & Pratta Complaint*”); *U.S. ex. Rel. Scott Clark v. Questcor Pharmaceuticals, Inc.*, 2:13-cv-01776-BMS (E.D.Pa.) at Document 1 (“*Clark Complaint*”).

10. Local 420 brings no overlapping claims against Mallinckrodt or UBC in this lawsuit for any alleged antitrust violations. Instead, it sues on behalf of itself and all similarly situated TPPs of Acthar for consumer fraud, RICO violations and other common law claims arising out of the unique distribution, pricing, marketing and sales schemes alleged herein, arising out of the unique claims alleged by several former employees of Mallinckrodt. The details of the conduct underlying these claims were only first revealed to Plaintiff and the Class in April 2019 when the *Strunck and Pratta Complaint* was unsealed by this Court.

11. Second, throughout the relevant time period, since August 2007 through the present, Mallinckrodt has willfully manipulated and inflated the prices paid by TPPs for Acthar, causing TPPs like Local 420 to substantially overpay for a drug with very limited uses and benefits and an unknown method of action (the “**Pricing Scheme**”). Specifically, after limiting Acthar distribution by the Distribution Scheme, in August 2007, Mallinckrodt agreed with CuraScript and UBC to raise the average wholesale prices (“**AWPs**”) paid for Acthar by TPPs like Local 420 from \$2,062.79 per vial to \$29,086.25, a more than 1,300% increase in the cost of Acthar in the span of one month. Such a price increase is both unprecedented and

¹ *See City of Rockford v. Mallinckrodt ARD, Inc., et. al.*, Case No. 17-cv-50107 (N.D.Ill.) (hereinafter the “**Rockford case**”).

unconscionable, especially for a more than 65-year old drug. Mallinckrodt, Curascript and UBC have continued to raise the AWP for Acthar each year, sometimes by double-digit percentages, such that now a drug that once cost \$40.00 costs patients and third-party payors over \$43,000.00. The only way Mallinckrodt has been able to get TPPs to pay such high prices for Acthar was through the fraudulent schemes alleged herein. But for such schemes, TPPs like Local 420 would not have paid what they did for Acthar.

12. Third, Mallinckrodt and UBC devised a marketing and sales scheme designed to ensure that Acthar was reimbursed by TPPs at the new, inflated AWP, without substantial backlash from patients and payors (the “**Marketing Scheme**”). Fearing an uproar of complaints from patients, patient support groups, private TPPs and the federal government for their unjustified distribution limitations and price increases, and in order to circumvent TPP cost containment mechanisms for high-priced specialty drugs, Mallinckrodt devised a multi-faceted scheme and RICO enterprise to bribe doctors in order to induce them to prescribe Acthar over other available treatments. The scheme involved cultivating key opinion leaders (or “KOLs”) from around the country to serve as the company’s “spokes-doctors” in promoting prescriptions of Acthar for unapproved uses and doses. The scheme also sought to remove patient complaints about high co-pays on Acthar by funneling tens of millions of dollars to UBC to run a so-called “patient assistance program” or “PAP” designed to ensure that private TPPs paid the bulk of the costs of Acthar.

13. On April 30, 2019, it was revealed publically for the first time by CNN² that two whistleblowers, both former pharmaceutical sales representatives for Mallinckrodt, had sued the company years before for a “multi-tiered strategy” to boost sales by bribing doctors to prescribe

² <https://www.cnn.com/2019/04/30/health/mallinckrodt-whistleblower-lawsuit-acthar/index.html>

the high-priced Acthar to their patients. As described more fully in the *Strunck & Pratta Complaint*, Mallinckrodt's scheme involved "using valuable incentives, rewards and other forms of remuneration to induce health care providers to promote and prescribe H.P. Acthar in lieu of less expensive therapies that are equally more effective...". *Strunck & Pratta Cmplt.* at ¶ 3(i). According to Strunck and Pratta, there is a pervasive culture at Mallinckrodt designed to sell Acthar at all costs.

14. Separately, a different whistleblower sued Mallinckrodt in this Court on April 4, 2013, alleging a different aspect of Mallinckrodt's scheme to sell Acthar at high prices. In a case unsealed as part of the government's filing of a consolidated, amended pleading, former employee Scott Clark alleges that "Mallinckrodt designed supposed 'patient assistance' funds that paid copays for Acthar only and then funded them through 'donations', knowing its money would be used on Acthar copays to the exclusion of other drugs." *See United States' Complaint in Intervention*, Dkt No. 2:13-cv-01776-BMS (E.D.Pa.) (BMS) at Document No. 57 ("*U.S. Complaint*") at ¶ 5. Such conduct is unlawful.

15. As the federal government has alleged:

"Mallinckrodt knew that the cost of Acthar would make it difficult to sell because there were cheaper, effective competitor drugs available to treat certain of its approved uses, namely acute exacerbations in multiple sclerosis, lupus and rheumatoid arthritis. Mallinckrodt intended to overcome this difficulty and did so by making the drug 'free' to patients by subsidizing their Medicare [and private] copayments. By doing so, Mallinckrodt could maintain the high price of Acthar to maximize its own sales revenues, but minimize the risk that the drug's high price would impede doctors and patients from using it."

Id. at ¶ 4 (brackets added).

16. Accordingly, in conjunction with limiting Acthar distribution and raising the prices for Acthar in 2007, as part of the Distribution and Pricing Schemes, Mallinckrodt also

embarked on a Marketing Scheme designed to incentivize sales of Acthar at the new high prices. Patients and TPPs had no choice but to pay the high prices charged by Mallinckrodt and UBC, Mallinckrodt's exclusive agent and "HUB".

17. Mallinckrodt vastly expanded its direct-to-consumer selling of Acthar by expanding its sales force, including creating a team of "medical science liaisons" or "MSLs". The MSLs were highly trained specialists in the Acthar treatments who worked with other Mallinckrodt sales representatives to create a network of KOLs. These KOLs were leading specialists in their respective medical fields whom Mallinckrodt identified as being potentially influential on other doctors. These KOLs were paid handsomely to join with Mallinckrodt's MSLs and sales representatives as "spokes-doctors", promoting Acthar to other medical providers and delivering Mallinckrodt's false, misleading and deceptive promotional messages about the safety, efficacy and value of Acthar in relation to other cheaper, safer, and equally or more effective treatments. As a result, thousands of new patients have been prescribed Acthar for unapproved uses and doses in the treatment of diseases in neurology, nephrology and rheumatology, among others. And TPPs have been force to pay the exorbitant prices charged by Defendants.

18. Local 420, other TPPs who have sued in state courts,³ and the Class of TPPs and their beneficiaries were harmed by Mallinckrodt's conduct. Specifically, in 2018, Local 420 paid for Acthar at the inflated prices charged by Defendants as a result of the Distribution, Pricing, and Marketing Schemes alleged. To date, Local 420 has paid \$152,798.92 for Acthar, more than it otherwise would have paid in the absence of Mallinckrodt's scheme and conspiracy.

³ One such TPP is the International Union of Operating Engineers Local 542 ("IUOE Local 542") based in Fort Washington, Pennsylvania. IUOE Local 542 sued Mallinckrodt and UBC in the Court of Common Pleas for Montgomery County, Pennsylvania in May 2018.

19. Local 420 brings this lawsuit on behalf of itself and a Class of all similarly-situated TPPs and their beneficiaries who paid for Acthar at prices based on the inflated AWP prices set by Mallinckrodt during the relevant time period between August 2007 and the present. Because some of the TPPs in the Class have already sued Mallinckrodt in state courts on their individual claims, Local 420 seeks to obtain declaratory and injunctive relief in this Court on behalf of a nationwide Class of all TPPs, in order to have the conduct of Defendants declared unlawful and enjoined, for the benefit of all affected TPPs and their beneficiaries. Local 420 also seeks to recover money damages for overpayments based on inflated AWP prices for Acthar, pursuant to federal RICO and the consumer protection laws of Pennsylvania and other states, as well as the common law of Pennsylvania and other states. Finally, Plaintiff seeks punitive damages for the Defendants' willful, outrageous and reckless conduct.

II. JURISDICTION AND VENUE

20. This Court has subject matter jurisdiction over this action pursuant to the Class Action Fairness Act of 2005, 28 U.S.C. § 1332(d), because Local 420 and members of the Class are diverse from the Defendants and over two-thirds of the Class is situated outside of Pennsylvania. Due to the exorbitant prices charged by Defendants for Acthar to the Class – currently over \$43,000.00 per prescription for a drug that used to cost a little more than \$2,000 -- the aggregate amount in controversy far exceeds \$5,000,000 for the Class.

21. This Court has personal jurisdiction over Plaintiff because it is located in Pennsylvania and it reimbursed for Acthar and other drugs in Pennsylvania.

22. This Court has jurisdiction over the Defendants because they are present and/or conduct substantial business in Pennsylvania, have registered to conduct business here, have had systematic and continuous contacts with Pennsylvania, and/or have agents and representatives

that can be found in Pennsylvania. The Court also has jurisdiction over multiple, unnamed co-conspirators who assisted Mallinckrodt in carrying out its scheme, including sales representatives, MSLs, and KOLs located in Pennsylvania as described herein.

23. The Court also has jurisdiction over the Defendants because they have had sufficient minimum contacts with and/or have purposefully availed themselves of the laws and markets of Pennsylvania through, among other things, their distribution, marketing and sales of Acthar to Local 420 and other residents of Pennsylvania.

24. Venue is proper in this District because Local 420 is situated in this District, and the Defendants transact business in this District. Venue is also proper because a substantial part of the events giving rise to Local 420's claims occurred in this District. Defendants also engaged in substantial conduct relevant to the claims of Local 420 and the Class, and caused harm to members of the Class in this District. Venue is also proper pursuant to 28 U.S.C. §1391.

25. Acthar is sold in both interstate and intrastate commerce, and the unlawful activities alleged in this Complaint have occurred in Pennsylvania and this District.

III. THE PARTIES

A. PLAINTIFF

26. Local 420 is a Taft-Hartley union fund providing health and welfare benefits to its members and their families. Local 420 has a business address at 14420 Townsend Road, Philadelphia, Pennsylvania 19154, which is situated in Philadelphia County, Pennsylvania.

27. Local 420 has represented the interests of working men and women in eastern Pennsylvania since 1935, including heavy equipment operators in the building and construction industry, along with C & D-Branch Division members who are employed at quarries, landfills, equipment dealers, shipyards, breweries, manufacturing plants, airports, bridges, and public

works.

28. Local 420 provides healthcare benefits to its employees through Independence Blue Cross (“IBC”). While IBC coordinates Local 420’s prescription drug benefits, including specialty drugs like Acthar, through Future Scripts, a pharmacy benefits manager (“PBM”), Local 420 is self-funded, meaning that Local 420 and its beneficiaries pay the full costs of drugs like Acthar.

29. The spouse of one such member of Local 420 has a medical condition, a rheumatic disorder, for which Acthar was prescribed for treatment. As described more fully herein, rheumatic conditions became a target of Defendant’s marketing and sales scheme to promote the sale of Acthar at artificially inflated prices. She received four separate prescriptions of Acthar in early 2018. Local 420 then paid for these administrations of Acthar at a net cost of \$38,199.73 for each such prescription. The net cost was based upon the inflated AWP of Acthar as set by Mallinckrodt.

30. The sum total of the 4 prescriptions paid for by Local 420 was \$152,798.92. The member/beneficiary was required to pay a co-pay of \$70.00 for each prescription, for a total of \$280.00. As a result, Local 420 has incurred a financial harm due to the Defendants’ conduct stated herein.

B. DEFENDANTS

31. Defendant Mallinckrodt ARD LLC (“Mallinckrodt”) has its principal place of business at 1425 U.S. Route 206, Bedminster, New Jersey 07921. Mallinckrodt ARD LLC was previously named Mallinckrodt ARD, Inc., and before that was named Questcor Pharmaceuticals, Inc. (“Questcor”).

32. Mallinckrodt ARD LLC is an indirect wholly-owned subsidiary of Mallinckrodt

plc, an Irish public limited company, with its corporate headquarters in Staines-upon-Thames, United Kingdom.

33. On April 4, 2014, Mallinckrodt plc entered into an Agreement and Plan of Merger with Questcor and effectuated the acquisition of Questcor on August 14, 2014 for approximately \$5.9 billion.

34. Following the merger, Questcor continued to market and sell Acthar, until changing its name to Mallinckrodt ARD Inc. on July 27, 2015.

35. On January 26, 2019, Mallinckrodt ARD, Inc. converted to Mallinckrodt ARD LLC and continues to market Acthar under that name today.

36. Defendant United BioSource Corporation n/k/a United BioSource LLC (“UBC”) is a Delaware corporation with its corporate headquarters at 920 Harvest Drive, Blue Bell, Pennsylvania 19422. UBC has been a wholly-owned subsidiary of Express Scripts from 2007, when it was known as HealthBridge. In 2012, UBC was acquired by Express Scripts as part of the Medco merger, and HealthBridge was renamed UBC. In November 2017, Express Scripts announced that it sold UBC to Avista Capital Partners, a private equity firm.

37. UBC is a wholly owned subsidiary of United BioSource Holdings, Inc., the interests of which are held by and through various privately held intermediary entities, which are ultimately owned by private investment funds sponsored by and/or affiliated with Avista Capital Partners and as-yet-unknown individuals associated with Avista Capital Partners.

38. UBC is Mallinckrodt’s exclusive “agent” designated to operate the Acthar Support and Access Program (“ASAP”), a program put in place in 2007 as part of the “new strategy” to manage the Acthar’s exclusive distribution and sales directly to patients. UBC is specifically identified as Mallinckrodt’s agent on the Acthar Start Form, which every patient and

health care provider (“HCP”) is required to fill out and sign prior to receiving Acthar. *See* 2018 Acthar Start Form at **Exhibit “A” hereto**.

39. UBC operates as the Mallinckrodt’s “HUB” of operations for Acthar distribution and payment, coordinating all aspects of the scheme and conspiracy, from the initial identification of patients, insurance and payment verification, through to payment by TPPs, like Local 420 and the Class.

40. The corporate Defendants’ acts alleged in this Complaint to have been done by each of the Defendants were authorized, ordered, done and/or ratified by their respective officers, directors, agents, employees or representatives while engaged in the management, direction, control or transaction of their respective business affairs.

IV. FACTUAL BACKGROUND

A. ACTHAR DEVELOPMENT AND LIMITED APPROVAL BY THE FDA

41. Acthar was approved by the FDA on April 29, 1952 for over 50 conditions, ranging from alcoholism, poison ivy, and radiation sickness to nephrotic syndrome. Over time, as discussed below, with additional evidence-based requirements for prescription drugs, the list was winnowed by the FDA to the fewer, present-day 19 indications.

42. Acthar is adrenocorticotrophic hormone (“ACTH”), which causes the body to produce cortisone and other steroid hormones. Two Mayo Clinic researchers, Drs. Philip Hench and Edward Kendall, developed the treatment, which won them the Nobel Prize for medicine at the time it was developed.

43. Acthar was developed by Armour Pharmaceutical Company. As described by the Seventh Circuit in *Armour & Co. v. Wilson & Co.*, 274 F.2d 143, 145-46 (7th Cir. 1960):

In a human being, . . . (ACTH) appears in the anterior lobe of the pituitary gland located at the base of the brain. When the human

body is under stress or attacked by certain diseases, control centers in the brain excite the pituitary, and the pituitary secretes ACTH. In the blood stream the ACTH thus secreted is carried to the adrenal glands situated in the human body above the kidneys. As the ACTH hits the outer wall of the adrenal glands, it stimulates the adrenals to produce a set of chemical substances such as steroids, including the hormones, cortisone and hydrocortisone.

The cortisone hormones then act in the tissues of the body to suppress inflammations and allergic reactions. ACTH thus is used to relieve such conditions as rheumatoid arthritis and allergies. ACTsH does not, itself, directly attack disease. However, it stimulates the adrenals which produce more than twenty-eight steroids, and these hormones attack the diseased tissues. When the human body itself does not supply sufficient ACTH, pharmaceutical ACTH can fill the gap.

44. In layman's terms, ACTH is a hormone released by the brain that triggers the adrenal glands to make cortisol, which is the body's equivalent of prednisone, a steroid. ACTH works by inducing a patient's adrenal glands to release cortisol, thereby replicating the effect of taking prednisone. Because of this, ACTH has risks and benefits similar to those of prednisone.

1. The FDA Regulates What Drugs May Be Marketed, and the Uses For Which They May Be Marketed.

45. Under FDCA 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a), (d). Approval of the drug by the FDA is the final step in a multi-year process of study and testing.

46. To determine whether a drug is "safe and effective," the FDA relies on information provided by a drug's manufacturer; it does not conduct any substantial analysis or studies itself. Applications for FDA approval (known as New Drug Applications or "NDAs") must include "full reports of investigations which have been made to show whether or not such drug is safe for use and whether or not such drug is effective in use." 21 U.S.C. § 355(b)(1)(A).

47. Under the nation's food and drug laws, a drug may not be introduced into interstate commerce unless its sponsor has shown that the drug is safe and effective for the intended conditions of use. 21 U.S.C. §321. The law requires that "adequate and well controlled investigations" be used to demonstrate a drug's safety and effectiveness. 21 U.S.C. § 355(d)(7). The FDA approves a drug if there are "adequate and well-controlled clinical trials" that demonstrate a drug's safety and effectiveness for its "intended conditions" of use. 21 U.S.C. § 355(d)(5). The "intended conditions" for use of a drug are listed in the drug's labeling, which is reviewed and approved by the FDA. 21 U.S.C. § 355(d)(1) & (2). Indications for use that are not listed in a drug's labeling have not been approved by the FDA. 37 Fed. Reg. 16,503 (1972). They are "unapproved" uses.

48. The standards that govern the FDA safety and effectiveness requirements are contained in statutes, regulations, notices and guidance documents. The statutory requirement that a drug's effectiveness be demonstrated by "adequate and well-controlled clinical investigations" has been interpreted to mean a clinical study with (1) clear objectives; (2) adequate design to permit a valid comparison with a control group; (3) adequate selection of study subjects; (4) adequate measures to minimize bias; and (5) well defined and reliable methods of assessing subjects' responses to treatment. 21 C.F.R. § 314.26.

49. The FDA also requires the need for reproducibility and reliability of clinical data in the trials that support a drug's approval. In order to address this requirement, the FDA generally requires two pivotal, adequate and well-controlled trials to support approval, except in certain circumstances. As stated by the FDA in its 1998 Guidance to the Industry, "it has been FDA's position that Congress generally intended to require at least two adequate and well controlled studies, each convincing on its own, to establish effectiveness." *See* U.S. Department

of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drugs and Biological Products, May 1998. *See also, Final Decision on Benylin*, 44 FR 51512, 518 (Aug. 31, 1979).

50. The FDA's position is based on the language in the statute and the legislative history of the 1962 amendments. Language in a Senate report suggested that the phrase "adequate and well-controlled investigations" was designed not only to describe the quality of the required data but also the "quantum" of required evidence. *See* S. Rep. No. 1744, Part 2, 87th Cong.2d Sess. 6 (1962).

51. In Section 115(a) of the Medicare Modernization Act, Congress amended section 505(d) of the Act to make it clear that the FDA may consider "data from one adequate and well-controlled clinical investigation and confirmatory evidence" to constitute substantial evidence if the FDA determines that such data and evidence are sufficient to establish effectiveness. In making this clarification, Congress confirmed FDA's interpretation of the statutory requirements for approval and acknowledged the FDA's position that there has been substantial progress in the science of drug development resulting in higher quality clinical trial data.

52. Cases in which the FDA has approved a drug on the basis of one clinical trial plus, confirmatory evidence are rare. They include instances of large, independently conducted multi-center trials with strong empirical results, with internal consistency across multiple outcomes, such that "sponsors faced ethical boundaries" in conducting a second placebo-based trial. Clinical trials that are not controlled, blinded, randomized and whose endpoints are not prospectively and objectively determined and measured may be used in early stage drug

development phases, but are exceptionally unlikely to qualify as “adequate and well-controlled” clinical trials needed to support FDA approval.

53. After a drug is approved, the FDA continues to exercise control over the product labeling. To protect patients from safety concerns, the FDA may require a label change to reflect the increased risk of various side effects or interactions, restrict a drug's indications, or, in extreme cases, force a withdrawal from the market. 21 C.F.R. § 201.57(3).

2. FDA Regulations Prohibit Off Label Marketing Through False and Misleading Statements About a Drug's Use or Benefits.

54. FDA regulations restrict how drug companies may market and promote approved drugs. *See* 21 U.S.C. §§ 331, 852; 21 C.F.R. § 314.81. Drug labels, including all marketing and promotional materials relating to the drug, may not describe intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331; 352. Illegal “misbranding” can result in criminal penalties. 21 U.S.C. § 333.

55. Drug companies such as Mallinckrodt must submit specimens of mailing pieces and any other labeling or advertising devised or used for promotion of the drug product at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product. Each submission is required to be accompanied by a completed transmittal Form FDA-2253. This constitutes a specific and material representation that all promotional items are being disclosed and provided to the FDA. Moreover, it constitutes an implied representation that the promotion and marketing that is being done through verbal communications, including inter alia, any drug company's speech or “advertisement” for the product, which are also subject to the prohibitions against off label marketing in 21 C.F.R. 202.1, is consistent and in line with any written communications being submitted to FDA.

56. The same general requirements about the promotion of prescription drugs apply to both professional and consumer-oriented marketing. In particular, promotional materials may only make claims that are supported by “substantial” scientific evidence (according to strict scientific procedures) and they may not be false, deceptive or misleading. FDA oversight helps ensure a “fair balance” in all promotional claims and materials. Federal regulations require that the risks as well as the benefits be clearly identified and given appropriate prominence. Promotional materials must be consistent with the FDA-approved product labeling. This restriction pertains to the clinical indications for which the drug has been approved as well as the dosing regimen that is supported by the clinical trials that were undertaken to establish safety and efficacy.

57. A drug company that wishes to market or otherwise promote an approved drug for uses other than those listed on the approved label, must resubmit the drug for a series of clinical trials similar to those required for the initial FDA approval. *See* Food and Drug Administration Modernization Act of 1997 (“FDMA”) 21 U.S.C. §§ 360aaa(b), (c); *see also* 21 C.F.R. § 814.54 (outlining the administrative procedure for filing an application for a new indication); 21 U.S.C. §§ 301, *et seq.* A supplemental NDA must be filed. Unless and until an additional indication is approved by the FDA, the unapproved use is considered to be “off-label.”

58. The term “off-label” refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified on the label, or treating a different patient population, *e.g.*, treating a child when the drug is approved to treat adults.

59. Although the FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication, the FDA does not regulate the practice of medicine. Once a drug is approved for a particular use, the FDA does not prohibit physicians from prescribing the drug for uses that are different than those approved by the FDA. When considering off-label prescribing, physicians are supposed to depend on the patient-specific evidence they have available to them. This should include the particular patient, the severity of his or her problems, the successfulness of prior treatment, and the risks of not treating. Whether contemplating on or off-label use, physicians also sometimes rely on personal experience, recommendations from colleagues and academics, educational seminars, and clinical trials evidence. Regrettably, much of what physicians rely on is information (or, as the case may be, misinformation) provided by sales representatives from drug makers, drug company sponsored continuing medical education (“CME”) courses and speaker programs, and drug company sponsored clinical trials.

60. Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved, or for a patient group that is unapproved. Specifically, a manufacturer illegally “misbrands” a drug if the drug's labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352. The statute, 21 U.S.C. § 331(d), and its implementing regulations, and 21 C.F.R. 202.1(e)(4)(i)(a) prohibit any advertising that recommends or suggests an off-label use for an approved drug, and the FDA has interpreted “advertising” to include a significant amount of speech that would not typically be considered advertising. *See* Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,074 (Dec. 3, 1997). The FDA “interprets the term ‘advertisement’ to include information (other than

labeling) that originates from the same source as the product and that is intended to supplement or explain the product.”

61. Any drug company's speech explaining one of its products is an “advertisement” for the product and is subject to the prohibitions against off label marketing in 21 C.F.R. 202.1, as well as the FDA’s “fair balance” requirement, described below. While a drug company may be entitled to certain First Amendment protection for truthful speech, *see U.S. v. Caronia*, 703 F.3d 149 (2d. Cir. 2012), off-label promotion that is false or misleading is not entitled to First Amendment protection. *Caronia*, 703 F.3d at 166 n. 10. *See Cent. Hudson*, 447 U.S. at 566, 100 S. Ct. 2343. Under 21 U.S.C. § 331(a), a defendant may be prosecuted for untruthfully promoting the off-label use of an FDA approved drug, *e.g.*, making false or misleading statements about a drug.

62. Section 202.1(e)(6)(xi) provides that an advertisement may not use “literature, quotations, or references for the purpose of recommending or suggesting conditions of drug use that are not approved or permitted in the drug package labeling.” *See also* 21 U.S.C. § 331(d) (prohibiting distribution of a drug for non-approved uses); *id.* at § 331(a) (prohibiting distribution of a misbranded drug); *id.* at § 360aaa (permitting dissemination of material on off-label uses only if the manufacturer meets certain stringent requirements).

63. The FDA regulations that fall under the general rubric of 21 C.F.R. 202.1(e)(6), *et seq.* ban advertisements that are false, lacking in fair balance, or otherwise misleading. Thus, the use of unsubstantiated comparative claims also is prohibited by law. 21 U.S.C. § 352; 21 C.F.R. § 202.1(e)(6).

64. Thus, companies like Mallinckrodt may not promote their approved drugs through unsubstantiated comparative claims that exalt their drugs as safer or more efficacious than

competitor drugs. Such promotion renders a drug “misbranded” and no longer eligible for reimbursement by government programs, including Medicare and Medicaid.

65. The regulations prohibit an advertisement that “contains a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience, by selective presentation of information from published articles or other references that report no side effects or minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated.” 21 C.F.R. 202.1(e)(6)(iv).

66. The regulations require drug companies to present a “true statement” of information relating to the side effects, contraindications and effectiveness of the drug use. 21 C.F.R. 202.1(e)(5), *et seq.* A company violates this regulation if it presents “false or misleading” information about a drug's side effects or does not “fair[ly] balance” information relating to the safety and efficacy of the drug use against information about its side effects and contraindications. *Id.*

67. Section 202.1(1)(2) broadly describes “labeling” of a drug as including any material accompanying a drug product that is supplied and disseminated by the manufacturer, packer or distributor of the drug.

68. Section 201.56 requires labeling to be “informative and accurate and neither promotional in tone nor false and misleading in any particular,” to “contain a summary of the essential scientific information needed for the safe and effective use of the drug,” and prohibits “implied claims or suggestions of drug use if there is inadequate evidence of safety or a lack of substantial evidence of effectiveness.”

69. The FDA has interpreted oral communications as falling under the umbrella of “labeling.”

70. Section 99.101, *et seq.* lays out the stringent requirements that must be met by the manufacturer before it may disseminate any materials on unapproved or new uses of marketed drugs. This material must be in the form of an unabridged reprint or copy of a published, peer reviewed article that is considered “scientifically sound” by experts qualified to evaluate the safety or effectiveness of the drug involved. *See* 21 C.F.R. 99.101(a)(2). The FDA does not consider abstracts of publications to be “scientifically sound” 21 C.F.R. 99.101(b). Unabridged reprints or copies of articles shall not be disseminated with any information that is promotional in nature. 21 C.F.R. 99.101(b)(2).

71. Furthermore, the manufacturer must not disseminate materials that are “false and misleading,” such as those that only present favorable information when unfavorable publications exist, exclude mandatory information about the safety and efficacy of the drug use, or present conclusions that “clearly cannot be supported by the results of the study.” 21 C.F.R. 99.101(a)(4).

72. Additionally, off-label information may be disseminated only in response to an “unsolicited request from a healthcare practitioner.” 21 U.S.C. § 360aaa 6. In any other circumstance, a manufacturer may disseminate information concerning off-label use only after it has submitted an application to the FDA seeking approval of the drug for the off-label use, has provided the materials to the FDA prior to dissemination; and the materials themselves are submitted in unabridged form and are neither false or misleading. 21 U.S.C. §§ 360aaa (b) & (c); 360aaa 1.

73. The FDA does not generally regulate the exchange of scientific information, but when such information is provided by or on behalf of a drug company regarding one of the company's products, the information may be subject to the labeling and advertising provisions of the law and regulations. For example, while information provided at continuing medical education programs (such as medical conferences and professional gatherings intended to enhance physicians' knowledge and enable them to meet certain practice requirements) generally is not subject to FDA regulation, it will be subject to FDA regulation if the program has been funded and substantially influenced by a drug company.

74. In sum, the off label regulatory regime of the federal government protects patients and consumers by ensuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific government body – the FDA. The prohibition on unsubstantiated comparative claims protects patients and consumers by ensuring that the prescription and use of approved drugs is not based on misleading marketing tactics.

3. The FDA has limited ability to regulate drug company marketing and promotion.

75. The FDA's Division of Drug Marketing, Advertising and Communications (“DDMAC”) is charged with overseeing the marketing and promotion of approved drugs to ensure that advertisements are not false or misleading, provide a fair balance between the benefits and risks of the drug, and do not include off label uses. *See* Statement by Janet Woodcock, M.D. (Director Center for Drug Evaluation and Research, FDA) Before the Senate Special Committee on Aging (July 22, 2003).

76. DDMAC's effectiveness in regulating off label promotion is limited. In 2003, the entire staff consisted of forty members, with twenty-five reviewers responsible for reviewing all drug advertisements and promotional materials. Moreover, drug materials do not have to be pre-

approved. FDA review of promotional materials occurs, if at all, only after the materials already have appeared in public. *See* Woodcock Statement, *supra*. Upon finding a violation, DDMAC generally requests, but does not require, the company to stop using the promotional materials. *Id.* Sponsors occasionally are required to publicly correct product misimpressions created by false, misleading, or unbalanced materials. *Id.*

77. Once a drug has been approved, the FDA's statutory authority is limited to requesting label changes, negotiating restrictions on distribution with the manufacturer, and petitioning for the withdrawal of the drug from the marketplace. Title 21 of the Code of Federal Regulations requires that "as soon as there is reasonable evidence of a serious hazard with a drug," the "Warnings" section of the label should be revised to reflect this hazard.

78. The FDA's ineffectiveness in policing off label promotion was confirmed in a July 28, 2008 U.S. General Accountability Office Report, which found that the FDA took an average of seven (7) months to issue letters in response to off-label promotions. *See* Drugs: FDA Oversight of the Promotion of Drugs for Off-Label Uses (GAO 08-835), <http://www.gao.gov/new.items/d08835.pdf>. Among the Report's findings: (i) FDA does not have separate oversight activities to specifically capture off-label promotion; (ii) FDA is unable to review all promotional submissions because of the volume of materials it receives and prioritizes its reviews in order to examine those with the greatest potential impact on human health; (iii) FDA is hampered by the lack of a system that consistently tracks the receipt and review of submitted materials; (iv) FDA conducts limited monitoring and surveillance to identify violations that would not be identified through its review of submitted materials, for instance, discussions between doctors and sales representatives; (v) during calendar years 2003 through

2007, FDA issued 42 regulatory letters in response to off-label promotions requesting drug companies to stop dissemination of violative promotions.

4. Mallinckrodt's false and misleading marketing of Acthar for a "mode of action" that is unknown, and for uses and doses that are not approved by the FDA.

79. According to the "Pre-Decisional Agency Memo" issued September 27, 2010 by the DDMAC for Acthar, NDA 022432 ("**DDMAC Memo**"), the formulation of ACTH now known as H. P. Acthar Gel (Repository Injection), which is known generically as corticotropin, was originally approved by the FDA *prior to* the 1962 Kefauver-Harris Amendment to the Federal Food, Drug And Cosmetics Act of 1962 ("FDCA"), which introduced the requirement of "substantial evidence" of two adequate and well controlled studies. ***See DDMAC Memo attached hereto at Exhibit "B" hereto.***

80. In its 2010 assessment of Acthar, the DDMAC observed:

At the time of the original approval drug manufacturers only had to show the drug was safe for use in humans. The original data included case reports from a few physicians describing patients with conditions originally treated with Acthar powder that were transferred to treatment with Acthar Gel and gave dosing guidance for treatment of these individual conditions. A few patients had improvements in hematology data and improvement in symptoms (decreased diarrhea, improved appetite, sense of well-being, etc.) reported to support the efficacy of treatment.

These data would be grossly inadequate to support approval of a new drug or new indications by the Agency under current standards requiring evidence from adequate and well-controlled clinical trials.

DDMAC Memo at 2-3 at Exhibit "B" (emphasis supplied).

81. Remarkably in 2017, Mallinckrodt falsely stated that when the FDA reviewed Acthar's label in 2010, it "determined there was sufficient scientific evidence and clinical evidence to support the 19 indications now in the current label." **Mallinckrodt Statement on**

H.P. Acthar Gel (Repository Corticotropin Injection) Update, dated June 22, 2017, attached hereto as Exhibit “C” (“Mallinckrodt 2017 Statement”). The Mallinckrodt 2017 Statement claimed to “[t]o address the false and misleading information about Mallinckrodt Pharmaceuticals and its product H.P. Acthar Gel,” when in point-of-fact, it did the opposite: it presented a demonstrably false and misleading picture about Acthar’s safety (including the increasing incidence of adverse events), efficacy and approval by the FDA.

82. In fact, directly contradicting Mallinckrodt’s false claims about the alleged “sufficiency of scientific evidence,” the Director of the Division of Neurology Products, Dr Russell Katz, wrote:

The **sponsor [Mallinckrodt] had not conducted any trials of its own**, and, in brief, we determined that the sponsor should attempt to obtain primary data for several trials published in the archival literature that, potentially, could provide substantial evidence of effectiveness for Acthar Gel for IS.

* * *

The data that the sponsor has provided differ considerably from that typically submitted in an NDA. As noted earlier, **none of the studies were commissioned or conducted by the sponsor, and detailed protocols, and, in particular, detailed statistical plans for the analyses of these studies, did not exist.**

April 5, 2010 Memorandum from Russell Katz, M.D. at 1, 9 (available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022432Orig1s0900SumR.pdf) (emphasis supplied).

83. Mallinckrodt continued to press its false and misleading narrative about the FDA’s purported “approv[al] for 19 indications ... following a full label review by the Agency in 2010” into 2018, when Local 420 began to pay for Acthar. *See* **Mallinckrodt Statement, “Facts About H.P. Acthar Gel, H.P. Acthar Gel Value to Patients” dated June 29, 2018 attached hereto as Exhibit “D” (“Mallinckrodt 2018 Statement”).**

5. **Acthar's DESI review and narrowing of approved indications due to a lack of proven efficacy and safety.**

84. Despite published reports that Acthar was somehow “grandfathered” by the FDA, in truth Acthar was subjected to a Drug Efficacy Study Implementation (DESI) review in the early 1970s. The FDA has always required proof of safety and efficacy for the approval of prescription drugs.

85. At the time of the 1962 amendments to the FDCA, there were thousands of drugs on the market whose effectiveness was suspect or altogether unknown. The amendments thus required the FDA to *withdraw* prior approval of a drug if it found: “on the basis of new information before [it] with respect to such drug, evaluated together with the evidence available to [it] when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof.” *FDCA, 21 U.S.C. § 355(e)*.

86. Acthar was thus subjected to a DESI review in 1971, and was **found to be effective only for a narrow subset of indicated uses**. The 1971 report titled “Corticotropin for Parenteral Use”, Federal Register, Vol. 36, No. 152 (Aug. 6, 1971) at 14509-14510, found Acthar “lacking substantial evidence of effectiveness” for its “recommended use” in over 30 of its originally approved indications. With respect to certain of the remaining indications, the FDA found Acthar “probably effective”; for others, the FDA found “these drugs are regarded as possibly effective for their labeled indications.” *Id.* at 14510.

87. In 1977, the FDA issued a “Follow Up Notice and Opportunity for Hearing”, Federal Register, Vol. 42, No. 40 (March 1, 1977) at 11891-11892, in which it reported:

[on] August 6, 1971, the [FDA] announced its conclusions that the drug products described below [including Acthar] are effective, probably effective, possibly effective, and lacking substantial evidence of

effectiveness for their various labeled indications. The notice provided an opportunity for a hearing for the indications concluded at the time to lack substantial evidence of effectiveness. **No data in support of any of the less-than-effective indications were submitted. All such indications are now reclassified to lacking substantial evidence of effectiveness. ...No person requested a hearing concerning them, and they are no longer allowable in the labeling.**

The drugs now lack substantial evidence of effectiveness for the indications evaluated as probably and possibly effective for the indications evaluated as probably and possibly effective in the August 6, 1971 notice.

Id. (brackets added)(emphasis supplied).

88. As a result, Acthar was left with about 19 narrow indications. For instance, in the area of “rheumatic disorders”, the disease for which Acthar was prescribed for Local 420’s beneficiary, Acthar was approved only “as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in ... rheumatoid arthritis”. *Id.* at 11892 (parenthetical in original).

89. All other indications had been “reclassified to lacking substantial evidence of effectiveness” by the FDA. Nevertheless, Mallinckrodt has continued to tout Acthar’s original approval in 1952 for “over 50 indications” in an effort to convince physicians, patients and TPPs that Acthar is widely approved to treat array of diseases, as opposed to just the 19 narrow indications for which it is actually approved. *See* listing of approved conditions below.

90. By the 1960s, Acthar was essentially a generic drug. Injectable ACTH medications faced a variety of competing products. *See Armour & Co. v. Wilson & Co.*, 274 F.2d at 145 (“Both Armour and Wilson manufacture and sell gelatin-ACTH preparations Gelatin-ACTH now constitutes more than 80% [o]f all forms of ACTH products sold by Armour and Wilson. Other companies . . . produce similar products”).

91. For the majority of the Acthar's drug lifespan, however, generic corticosteroids, such as prednisone, effectively treated the majority of the indications for which Acthar was approved. That factor tended to limit the market for Acthar to treating infantile spasms ("IS") which was originally an "off-label" indication. Consequently, because of the limited, off-label market for Acthar, by 2001, the drug was priced at \$40 per vial and accounted for less than a million dollars of revenue for Aventis, the then-owner.

92. Because prednisone is equally efficacious as Acthar, it has the same risks and benefits as Acthar, but at a far cheaper price. According to GoodRx.com, prednisone is available at leading retail pharmacies for little more than \$4 (with coupons), including Walmart, Target, CVS, Walgreens and Giant.

93. Despite this, Mallinckrodt has continually marketed Acthar as the new and improved prednisone, but without any support through head-to-head studies with prednisone. While prednisone has been proven to be safe and effective for the vast majority of indications on Acthar's label, there is no data to support Mallinckrodt's claims that Acthar is equally or more efficacious than prednisone, or other corticosteroids, so as to warrant even the same price as prednisone, let alone the exorbitant price of Acthar.

94. The same is true of Solu-Medrol (methylprednisone), a synthetic corticosteroid used to treat some of the same conditions for which Mallinckrodt promotes Acthar. Specifically, Solu-Medrol is given to people with multiple sclerosis ("MS") to shorten relapses. The cost of Solu-Medrol is around the same price as what Acthar used to cost, before Mallinckrodt acquired the product in 2001.

95. To try to deflect attention from the stark price differences between Acthar and generic prednisone, Mallinckrodt has engaged a small army of dedicated, highly-paid spokes-

doctors as KOLs to work with Mallinckrodt MSLs and its large sales force to promote sales of Acthar to the KOLs' peers. These KOLs work with Mallinckrodt and UBC to circumvent and bypass protections and controls imposed by TPPs to control and limit their expenditures on high-priced specialty drugs, like Acthar.

96. One major control utilized by payors is a "prior authorization" ("PA") process whereby a prescription for high-priced specialty medication like Acthar must be reviewed and authorized *before* the script written by the doctor is filled and charged to the TPP. However, Mallinckrodt and UBC have systematically circumvented such controls by their insistence that all patients and providers signing the blanket consents included on the Acthar Start Form at **Exhibit "A" hereto**, put in place in 2007 as part of the "new strategy". All such forms are faxed to UBC and processed through the "HUB" as described below, ensuring that unapproved uses and doses, like those prescribed to the beneficiaries of Local 420, IUOE Local 542, and other TPPs in the Class, are paid for at Mallinckrodt's inflated AWP.

6. Acthar's approved label indications.

97. As stated above, the FDA has approved Acthar for multiple, but limited, indications. These narrow indications, as set forth in the FDA-approved label, are:

- a. As monotherapy for the treatment of infantile spasms ("**IS**") in infants and children under two years of age;
- b. For the treatment of acute exacerbations of Multiple Sclerosis ("**MS**") in adults;
- c. As adjunctive therapy for short term administration (to tide the patient over an acute episode or exacerbation) in the following Rheumatic Disorders: Psoriatic arthritis, Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), Ankylosing spondylitis (collectively, "**RA**");

- d. During an exacerbation or as maintenance therapy in selected cases of the following Collagen Diseases: systemic lupus, erythematosus, systemic dermatomyositis (polymyositis)(collectively, “SLE”);
- e. For the following Dermatologic Diseases: Severe erythema multiform and Stevens-Johnson syndrome;
- f. For serum sickness;
- g. For symptomatic sarcoidosis;
- h. To induce a diuresis or a remission of proteinuria in the nephrotic syndrome (“NS”) without uremia of the idiopathic type or that due to lupus erythematosus.

98. Despite these many, narrow indications, substantially all of Mallinckrodt’s sales have been generated from just five of these indications: (1) IS, (2) MS, (3) SLE, (4) NS, and (5) RA.

7. Multiple Sclerosis (MS), Systemic Lupus Erythematosus (SLE), Nephrology Syndrome (NS) and Rheumatoid Arthritis (RA).

a. Multiple Sclerosis

99. Multiple sclerosis (“MS”) is a central nervous system disease in which the body’s immune system attacks the body’s myelin nerve cell coating. MS can cause a variety of symptoms, which can increase in severity periodically.

100. MS “relapses,” “acute exacerbations,” or “flares” (collectively “MS exacerbations”) are temporary periods of increased disease activity in an MS patient, manifested by the worsening of existing MS symptoms or the onset of other MS symptoms. MS exacerbations are not a separate disease from MS.

101. The FDA has approved several medications for the long-term treatment of MS patients, including medications to slow the accumulation of physical disability from the disease or to decrease the frequency of acute exacerbations. These medications are sometimes referred

to as MS “disease modifying” drugs or therapies. Acthar is not a “disease modifying” drug or therapy for MS.

102. The FDA also has approved drugs for treatment of MS exacerbations, such as Acthar. A standard treatment for MS exacerbations includes administering methylprednisolone, a steroid, which can be administered intravenously (“IVMP”) or orally. One such treatment is Solu-Medrol. Both IVMP and oral methylprednisolone are available in several brand name or generic forms. The drugs are significantly less expensive than Acthar. Depending on the pharmacy from which it is obtained, generic methylprednisolone can be had for as little as \$34 per gram, without coupon.

b. Systemic Lupus Erythematosus

103. Systemic lupus erythematosus (“SLE”) is an autoimmune disease in which the body's immune system targets its own healthy cells. Lupus can damage the kidneys, brain, skin, joints, or other areas of the body.

104. SLE patients can experience “flares” or “exacerbations” (collectively “SLE exacerbations”), which are periods of increased disease activity and are characterized by worsening SLE symptoms.

105. SLE exacerbations are not a separate disease from SLE.

106. A standard treatment for SLE exacerbations includes the administration of steroids, which can be available in brand name or generic forms. The drugs are significantly less expensive than Acthar.

c. Nephrology Syndrome

107. Nephrology syndrome (“NS”) is a kidney disease that causes one’s body to excrete too much protein in the urine. NS is usually caused by damage to the clusters of small blood vessels in one’s kidneys that filter waste and excess water from the blood.

108. A standard treatment for NS includes the administration of steroids, which can be available in brand name or general forms. The drugs are significantly less expensive than Acthar.

d. Rheumatoid Arthritis

109. Rheumatoid arthritis (“RA”) is an inflammatory autoimmune disease in which the body's immune system targets itself, including the joints. RA patients can experience “flares” or “exacerbations” (collectively, “RA exacerbations”), which are periods of increased disease activity and are characterized by worsening RA symptoms.

110. RA exacerbations are not a separate disease from RA.

111. A standard treatment for RA exacerbations includes the administration of steroids, which can be available in brand name or general forms. The drugs are significantly less expensive than Acthar.

8. Dangers of Acthar for unapproved uses and doses

112. Acthar is a dangerous drug with wide ranging and potentially life-threatening adverse effects. Thus, its FDA-approved label specifically warns that patients taking Acthar may suffer the following adverse effects:

- a. increased susceptibility to new infection and increased risk of exacerbation, dissemination or reactivation of latent infections, although signs and symptoms may be masked;
- b. adrenal insufficiency;

- c. Cushing's Syndrome;
- d. elevated blood pressure;
- e. masking of symptoms of other underlying diseases and disorders;
- f. gastrointestinal perforation and bleeding;
- g. behavioral and mood disturbances, including euphoria, insomnia, mood swings, personality changes, severe depression and psychosis;
- h. comorbid diseases, such that symptoms of diabetes and myasthenia gravis may be worsened;
- i. ophthalmic effects, such as cataracts, infections and glaucoma;
- j. loss of endogenous activity;
- k. enhanced hypothyroidism or liver cirrhosis for patients already suffering from these conditions'
- l. negative effects on pediatric growth and physical development;
- m. decrease in bone density; and
- n. potential fetal harm in patients who are pregnant, or may become pregnant.

113. Additionally, the FDA-approved label warns that patients taking immune suppressive doses of Acthar should not be administered live or attenuated vaccines.

114. In view of Acthar's unusual safety profile, the FDA took the additional, non-standard step when it approved Acthar for the treatment of IS in 2010 of also approving a Risk Evaluation and Mitigation Strategy (REMS) that requires Mallinckrodt to distribute an approved Medication Guide with each prescription, and also to submit REMS Assessments to the FDA at periodic intervals following approval of the REMS. The approved Medication Guide elaborates on the serious and significant side effects associated with Acthar.

115. As set forth below, the case of Patient A demonstrates how Defendants scheme directly impacted patient safety, contrary to the FDA-approved Acthar label.

B. THE ACTHAR “DISTRIBUTION SCHEME”

1. Questcor acquires Acthar from Aventis.

116. In 2001, Questcor acquired Acthar from Aventis Pharmaceutical Products, Inc. (“Aventis”) for only \$100,000, but in 2014 Mallinckrodt acquired Questcor for approximately \$5.9 billion.

117. In the July 27, 2001 Asset Purchase Agreement between Aventis and Questcor, Questcor acknowledged that there were risks in the transaction due to the limited approved indications for Acthar. Indeed, Questcor and Aventis held a meeting with FDA on February 7, 2001 in which such issues were discussed. Nevertheless, Questcor went through with the purchase.

118. Acthar’s value was limited because it was the “gold standard” for treating only one condition, infantile spasms (“IS”). IS is a serious condition in infants, but one with an annual patient population of less than 2,000 children per year. However, Acthar was not originally approved by the FDA to treat IS, further limiting its value. In 2010, the IS indication was approved by the FDA, and orphan drug status was granted.

119. Between 2001 – 2007, Acthar’s primary sales were for the treatment of IS, despite its off-label indication.

2. Sigma Tau’s Ownership and Control of Questcor, and the Launch of the “New Strategy”.

120. In 2001, Questcor was floundering as a company until it got millions of dollars from Sigma Tau Finanziaria, an Italian drug conglomerate run by brothers Claudio and Paolo Cavazza, giving the Cavazzas and Sigma-Tau approximately 31% of the common stock outstanding as of March 15, 2002 and making them the largest shareholder in Questcor. Indeed,

in its 2001 10-K, Questcor admitted that “these shareholders can control the outcome of certain shareholder votes, including votes on election of directors, ... and other significant corporate transactions.”

121. In addition, the Cavazzas owned warrants to purchase another 2,559,494 shares of common stock, as well as a \$2.0 million 8% convertible debenture, giving them even greater control over Questcor and its decision-making.

122. According to Questcor’s public filings, the company reported the following:

In April 2001, we entered into a Stock and Warrant Purchase Agreement with Sigma-Tau Finance Holding S.A. (“Sigma-Tau”) pursuant to which Sigma-Tau purchased (i) an aggregate of 2,873,563 shares of common stock at a purchase price of \$0.52 per share, for an aggregate purchase price of \$1,500,000, and (ii) a warrant to purchase an additional 2,873,563 shares of common stock at a purchase price of \$0.52 per share. In May 2001, as required under the rules of AMEX, we sought and received shareholder approval to allow for full exercise of the warrant. In July 2001, Sigma-Tau assigned the warrant to Paolo Cavazza and Claudio Cavazza, the principal shareholders of Sigma-Tau, who exercised the warrant in full, purchasing 2,873,563 shares of common stock at a purchase price of \$0.52 per share, resulting in aggregate proceeds to us of \$1,500,000 (including the \$100,000 originally paid by Sigma-Tau to acquire the warrant).

In July 2001, concurrent with our agreement to acquire Acthar from Aventis, we entered into a Stock Purchase Agreement with Sigma-Tau pursuant to which Sigma-Tau purchased 5,279,034 shares of common stock at a purchase price of \$0.66 per share, for an aggregate purchase price of \$3,500,000.

In December 2001, we entered into a Promotion Agreement with VSL Pharmaceuticals, Inc., a private company owned in part by the principal shareholders of Sigma-Tau, to promote, sell and distribute the product VSL#3 in the U.S. In connection with this Promotion Agreement, we entered into two Stock and Warrant Purchase Agreements, one with Paolo Cavazza and one with Claudio Cavazza, to purchase (i) an aggregate of 640,000 shares of common stock for a purchase price of \$1.50 per share (representing a twenty percent premium to our market price for the five days prior to execution of the Purchase Agreements), for an aggregate purchase price of \$960,000, and (ii) warrants, at an aggregate purchase price of \$300,000, to purchase an additional 1,800,000 shares of common

stock at a purchase price of \$1.75 per share before December 1, 2003. We issued the common stock related to this transaction in February 2002. Additionally, in connection with this transaction, we entered into a standstill agreement with Sigma-Tau whereby Sigma-Tau and its affiliates agreed to limit purchases of common stock on the open market to no more than 2,000,000 shares through July 2003. Assuming Sigma-Tau exercises its warrants in full, they would own approximately 34% (including the 640,000 shares of common stock issued in February 2002) of our outstanding common stock as of December 31, 2001.

On March 15, 2002, in two separate transactions, we issued \$4.0 million of 8% convertible debentures to an institutional investor and Sigma-Tau. We will pay interest on the debentures at a rate of 8% per annum on a quarterly basis. The debentures are convertible into shares of our common stock at a fixed conversion price of \$1.58 per share (subject to adjustment for stock splits and reclassifications). At the end of the term of the debenture, under certain circumstances, we have the option to repay the principal in stock and, under certain circumstances, we can also redeem the debenture for cash prior to maturity. The debentures mature on March 15, 2005. In conjunction with this transaction, we issued warrants to both the institutional investor and Sigma-Tau to acquire an aggregate of 1,518,988 shares of common stock at an exercise price of \$1.70 per share. Both warrants expire on March 15, 2006....

123. Importantly, a few years earlier, Claudio Cavazza had earned notoriety, and 1 ½ years of probation, for his role in a 1993 scandal in which he admitted paying kickbacks to health officials to get Sigma Tau products onto Italy's national drug formulary at increasingly higher prices. He also reportedly delivered bribes on behalf of other drug companies.

124. But Claudio's criminal record, a record of bribes to force payers to overpay for prescription drugs, did not stop Questcor from taking the Cavazzas' money and ceding effective control of the company to the Cavazza brothers in conjunction with Questcor's acquisition of Acthar.

125. Instead, Questcor allowed the Cavazzas to build their ownership stake in Questcor to more than 30%, giving them substantial control over Questcor's Board of Directors.

126. The Cavazzas used that control to install one of their own, Gregg LaPointe, to the Questcor Board of Directors.

127. In 2001, LaPointe was the Vice-President of Finance for Sigma Tau Pharmaceuticals, Inc. of Gaithersburg, Maryland (“Sigma-Tau Pharma”). Sigma Tau Pharma was the wholly-owned, U.S. subsidiary of Sigma-Tau. By 2003, LaPointe was the Chief Operating Officer (“COO”) of Sigma Tau Pharma. He was elevated to CEO in April 2007, in conjunction with his adoption of the below-described “new strategy” for Questcor’s sale of Acthar.

128. With the Cavazzas effectively in control, and now with LaPointe on the Questcor Board, the situation was ripe for fraud and abuse with Acthar, the likes of which have never been seen before, especially with a prescription drug of such limited therapeutic value.

3. Mallinckrodt Adopts a "New Strategy" to Restrict Acthar Distribution and Aggressively Market Acthar for Unapproved Uses and Doses Through a Scheme of Kickbacks and Inducements

129. Acthar is a specialty pharmaceutical distributed directly to patients, like the beneficiaries of Local 420 and IUOE Local 542 in this case.

130. For decades, Acthar was distributed to any doctor, hospital, wholesaler or specialty pharmacy who requested the drug to treat seriously ill patients. After Questcor acquired the rights to Acthar, it initially maintained that broad distribution network.

131. However, on July 2, 2007, Mallinckrodt restricted its distribution from three wholesalers, termed Wholesalers “A”, “B”, and “C” in its 2007 10-K, to just Express Scripts.

132. The goal of this “new strategy” was to lock patients into receiving Acthar through one distribution channel controlled by Mallinckrodt, and to ensure prescription distribution and

payment through one source, UBC. UBC is Mallinckrodt's self-described "HUB" of operations for Acthar. Mallinckrodt has maintained this exclusive arrangement with UBC since 2007.

133. However, the original officers and directors of Mallinckrodt did not agree with the "new strategy". Accordingly, two Directors on the Mallinckrodt Board engineered a coup to take over the company, to replace the CEO and to have the company adopt the new strategy.

134. Mallinckrodt's "new strategy" was the brainchild of Defendant Gregg LaPointe, a critical member of the Questcor Board of Directors installed by the largest shareholders, the Cavazzas. LaPointe also served as a member of the Corporate Council of the National Organization for Rare Diseases ("NORD"), which served as an important player in Mallinckrodt's and UBC's scheme to minimize resistance and pushback by patients and physicians to Acthar's higher prices by serving as a leading distributor of free Acthar supplied by Mallinckrodt to patients who could not afford to pay the newly established new high prices.

135. LaPointe convinced Steve Cartt, Questcor's Chief Operating Officer and Executive Vice-President in charge of sales and marketing of Acthar at the time, that the company should implement the "new strategy" for Acthar.

136. Cartt and LaPointe approached then-Questcor Board member Don Bailey to garner his support for the new strategy. Their "offline discussions did not sit well with Questcor's President and CEO at the time, James L. Fares.

137. In February 2005, James L. Fares was appointed President and CEO of Questcor by the Board of Directors. According to Albert Hanson, the Chairman of the Board, "the Board sought an accomplished pharmaceutical executive with substantial expertise in selling and marketing pharmaceutical products." Chairman Hanson further explained the selection of Feres as follows:

[T]he Board assessed each candidate's track record and capability to think creatively about Questcor's business. Such skills are critical in developing and executing a successful long-term strategy for a specialty pharmaceutical business. We looked for a talented executive who understood the specialty pharmaceutical market and had demonstrated the leadership skills necessary to create shareholder value. We believe that in Jim Fares we have found that executive. His successful track record in sales, marketing, business development, and general management, coupled with his energy and enthusiasm for pharmaceuticals, convinced us that we had found the right individual to lead Questcor.

138. Prior to joining Mallinckrodt, Feres held senior management positions at Merck, Athena Neurosciences and Elan Pharma. He founded and served as Sr. Vice President of Commercial Operations at Xcel Pharmaceuticals from 2001 – 2003. In his last position, he served as CEO and President of FGC Pharm/Novella Neurosciences. In sum, Feres was well qualified to lead a company like Mallinckrodt.

139. Feres resigned in May 2007, after taking the below-described 30% price increase for Acthar in February 2007. He was replaced by Don Bailey, whom the Board first appointed as Interim President, but then elevated to full-time President and CEO in conjunction with Mallinckrodt's adoption of the new strategy.

140. In sum, Bailey was not well qualified to lead a prescription drug company like Mallinckrodt. But he was willing to jettison responsible and ethical business practices in favor of the “new strategy”, with unconscionable price increases [the Pricing Scheme] and an aggressive campaign of off label promotion fueled by misrepresentations and deception about Acthar's price, MOA, approved indications and doses, and value. For that, he was rewarded by being appointed the company CEO.

141. Mallinckrodt then signed contracts with Curascript and UBC in late June 2007 for the exclusive distribution of Acthar and exclusive operation of the HUB for ASAP.

142. Mallinckrodt and UBC then began to promote Acthar aggressively pursuant to the Pricing Scheme and Marketing Scheme detailed below. They did so to overcome resistance by providers, patients, and TPPs (like Local 420) to the high cost and limited value of Acthar.

143. Shortly thereafter, in July 2007, three Board members resigned, including the Chairman Albert Hanson.

144. In addition to CEO Feres, Mallinckrodt's Sr. Vice President of Strategic Planning and Communications, Eric Liebler, also quit. Liebler quit less than a year after being hired. He quit just three weeks after the "new strategy" was announced.

145. LaPointe also resigned within a week of the new strategy being launched, but not because he disagreed with the new strategy. Quite the contrary: his work on behalf of the Cavazzas was done. The Cavazzas had accomplished what they set out to do, engineering a coup at Questcor to take the company on an aggressive path centered around the new strategy and the three schemes detailed herein, the Distribution Scheme, the Pricing Scheme and the Marketing Scheme. Without LaPointe's installment on the Questcor Board, this would not have been possible.

146. These facts were confirmed by Questcor COO Steve Cartt on September 6, 2007, when he wrote to all senior staff at Questcor the following about LaPointe's departure:

Subject: Lapointe departure

Wanted to give you all a heads-up that Gregg LaPointe has left the Board of Directors (see attached link). This has been expected for some time actually, and is no cause for concern. Gregg joined the Board so that Sigma Tau could have some visibility on how Questcor was being run and the strategy going forward for the company. He actually as you can imagine ended up spending far more time on Questcor business over the last year than he ever imagined. Sigma Tau, our largest shareholder, is now comfortable with the company's path forward now, and is interested in having Gregg fully focused on Sigma Tau's own US business going forward, so the decision was made.

Also, in case you were wondering, Gregg has been a big supporter of the pricing strategy from the very beginning, so his departure was not the result of any disagreement with strategy. Quite the contrary actually.

Let me know if you have questions. Thanks, Steve.

147. It is believed and therefore averred that this mass exodus of leading executives and Board members was caused by Mallinckrodt's decision to adopt the "new strategy", with the Distribution Scheme, the Pricing Scheme and the Marketing Scheme as the hallmarks of an overarching scheme to raise Acthar prices, and overcome TPP resistance to high drug prices.

148. The decision to change the distribution, pricing and marketing strategies for Acthar was highly lucrative for all who supported it.

149. For instance, between 2006-2007, Don Bailey was permitted to purchase tens of thousands of shares of Questcor stock for \$1.67 per share. He also received warrants to buy tens of thousands of additional shares of stock at just \$0.44 per share. After the new strategy was pushed through, and the company started gouging patients and payers for Acthar, Bailey sold his shares, making tens of millions in profits.

150. Bailey's last warrant exercise and sale of Questcor stock took place in the summer of 2014, just prior to Mallinckrodt's purchase of Questcor. He exercised warrants to purchase 40,000 shares of common stock at \$5.12 (at a total cost of \$204,800). He then sold the same stock one month later at \$91.96 per share (at a total price of \$3,678,240). This was a profit of more than \$3.2 million in one month!

151. All told, Don Bailey earned tens of millions of dollars in just over 7 years through his insider stock sales alone, not counting his lucrative executive and Board member package of salary and benefits.

152. The self-described “orphan drug strategy” worked as follows: despite the fact that Acthar was an older drug, Mallinckrodt would “re-launch” Acthar with a new, limited distribution system and a substantially higher price, to make it appear as if Acthar were a new product being launched as the only product indicated for IS, an off-label indication at the time.

153. The IS market was a captive market involving a life-threatening disease afflicting infant children. Like other debilitating or life-threatening, orphan conditions, for which there was only one, sole-source drug treatment, IS presented Mallinckrodt with an opportunity to leverage its position against a particularly fragile, powerless patient population in an extremely narrow market.

154. As a result, Mallinckrodt predicted that the IS market would likely be able to absorb a much higher price with little resistance. In contrast, Mallinckrodt feared that the market for drug treatments of other disease states, such as the MS market, would not tolerate such a high price. Nevertheless, Mallinckrodt only viewed the anticipated resistance to higher prices by patients and payors as a challenge to be overcome.

155. Mallinckrodt and UBC overcame such challenge in several ways, as part of a new marketing and sales scheme, including the following:

- (i) knowingly disregarding federal laws and FDA regulations prohibiting off-label marketing and promotion;
- (ii) knowingly misrepresenting the purported efficacy, safety and value of Acthar for the treatment of unapproved conditions and unapproved doses in promotional and marketing material not submitted to, reviewed by, or approved by the FDA;
- (iii) failing to disclose and submit to the FDA all of their promotion, advertisements and marketing materials, as required by law;
- (iv) promoting the sale of Acthar for uses that were not proven to be safe or effective, as required by law;
- (v) promoting the sale of Acthar for doses that were not proven to be safe or

effective, as required by law;

(vi) willfully underreporting adverse events, as required by law;

(vii) utilizing improper, false and misleading comparative marketing tactics, such as comparing Acthar to prednisone, and including unsubstantiated superiority and value claims; and

(viii) improperly compensating healthcare professionals with free vials of Acthar, speaking and consultant fees and benefits, and other kickbacks as an inducement to induce them to promote and prescribed Acthar to their patients.

(ix) operating patient assistance programs as a means to secretly channel funds to third parties to pay for patient copay obligations, to remove patient complaints about the high costs of Acthar, and to force TPPs like Local 420 to pick up the balance of the Acthar bill.

156. The new pricing established by Mallinckrodt under the Pricing Scheme was only limited by what Mallinckrodt predicted that payors, like Local 420, would be willing to bear. This was because the Marketing Scheme adopted at the same time ensured that the promotional message delivered by UBC, as well as Mallinckrodt sales representatives and MSL's, was false, misleading and deceptive, and backed by unlawful kickbacks and inducements.

157. Mallinckrodt Executive Vice-President, Steve Cartt, admitted “[w]e did some market research,’ . . . [t]alking to physicians and others about pricing ‘gave us some comfort that the [new] strategy would work, and physicians would continue to use the drug, and payers would pay’ ‘The reality was better than we expected.’”⁴

4. The Acthar Support & Access Program and the UBC “HUB”.

158. One of the primary means by which Defendants carried out their unlawful scheme and conspiracy was through a program known as the “Acthar Support & Access Program” or “ASAP.” This program was structured to ensure that Mallinckrodt could ship its Acthar directly

⁴ Milt Freudenheim, *Benefit Managers Profit by Specialty Drug Rights*, New York Times, C1, April 19, 2008 (titled The Middleman's Markup in New York Print Ed.)(hereinafter, “*Freudenheim*”).

to patients, and then receive guaranteed payments directly from the TPPs who provide prescription drug coverage for their beneficiaries.

159. The ASAP was adopted by Mallinckrodt and UBC in 2007, as part of the “new strategy”. UBC’s predecessor became the exclusive operator of the ASAP program for Mallinckrodt.

160. Under the ASAP, all Acthar prescriptions are routed through UBC to patients, and all Acthar payments are coordinated by UBC to Mallinckrodt.

161. This process is generally laid out in the Acthar Start Form provided by Mallinckrodt (at Exhibit A hereto).

162. Once the patient (or their physician) seeks a prescription of Acthar, they are directed to UBC by Mallinckrodt’s sales representatives, MSLs or KOLs. They are then required to fill out and fax back to UBC the Acthar Start Form in order to obtain Acthar. There is no other way to get Acthar.

163. Upon receipt of the Acthar Start Form, UBC confirms the prescription by the provider and the associated specialty pharmacy, and then confirms the patient’s insurance coverage or other source of payment. UBC then arranges for the Acthar to be delivered directly to the patient by CuraScript.

164. Copies of the Acthar Start Form are attached to the Strunck & Pratta Complaint at Exhibit “H” and “I”. These Qui Tam Relators have confirmed that this is the process for Acthar.

165. The Acthar Start Form requires the patient and the physician to authorize the prescription as “medically necessary”, and to payment as appropriate before Mallinckrodt will ship the Acthar to the patient. Mallinckrodt have used a version of the Acthar Start Form for all

year from 2007 through the present. For this entire time period, such forms are required to be faxed to UBC, via the used of the wires.

166. The Acthar Start Form consists of 3 sections: (1) a section requiring signature by the “HCP” (or health care professional); (2) a patient authorization requiring signature by the “patient or legal representative”; and (3) information concerning Acthar indications and usage. The required signature of the patient authorizes “Mallinckrodt and its agents” to do a number of things in relation to the prescription and distribution of Acthar. It further authorizes Mallinckrodt and its agents, “including Mallinckrodt reimbursement support personnel and United BioSource Corporation (“UBC”) or any other operator of the Acthar Support Access Program on behalf of Mallinckrodt (collectively, ‘Designated Parties’)” to provide Acthar and receive payment, among other things.

167. Specifically, the patient authorizes Mallinckrodt and UBC, its “Designated operator”, “to provide certain services to [the patient], including reimbursement and coverage support, patient assistance and access programs, medication shipment tracking, and home injecting training.” In other words, the patient directly authorizes UBC, as Mallinckrodt’s agent, to ship Acthar directly to them, and to receive payment from both the patient (for the co-pay) and the TPP prior to obtaining the medication.

5. Direct Injury of Plaintiff and the Class.

168. By the above-stated arrangements, Acthar product flows from Mallinckrodt to the patient, while the money flows from the patient and payor back to Mallinckrodt.

169. Mallinckrodt only “consigns” the Acthar to CuraScript, meaning that Mallinckrodt remains at risk for the sale of the product until it is shipped. Mallinckrodt maintains all right, title and interest to the Acthar until it is approved for delivery by UBC to the

patient and payment is assured by the TPP. Both possession and title pass to Acthar pass from Mallinckrodt to the patient and TPP, only after they both agree to pay for it via the Acthar Start Form and UBC's sign-off. UBC's role is to ensure that Mallinckrodt's "risk" is minimal because it will not authorize shipment until payment by the TPP is confirmed. At no time is either CuraScript or UBC at risk for the Acthar sold by Mallinckrodt.

170. In this way, TPPs like Local 420 and IUOE Local 542, along with other similarly situated members of the Class, are directly harmed by the conduct of the Defendants, because their beneficiaries receive the Acthar directly from Mallinckrodt, via its designated consignees, at their homes to be self-injected, and they make their co-payments, along with the TPPs, directly back to Mallinckrodt through this same arrangement.

171. This is a distinguishing feature of specialty drugs in general, from other brand name and generic drugs available at retail pharmacies, who received the drugs from wholesalers, who directly contract with drug manufacturers. Here, Mallinckrodt and UBC removed all the middlemen. There are no wholesalers or retailers between the patients and TPPs and the Defendants.

172. Further, Plaintiff and TPP members of the Class have paid the inflated AWP's directly set and charged by Defendants. As a result, their injury is both cognizable – economic injury from a price overcharge – and direct – paying the price set and charged by the Defendants sued. The Class does not include any other potential payors who may have paid some other price than the inflated AWP's for Acthar.

173. Mallinckrodt and UBC also uniquely interact directly with TPPs and their beneficiaries in this case to ensure their scheme is successful. Beyond direct consultation, they provide "Home Injection Training Services" or "HITS", by which Mallinckrodt pays to have a

nurse visit the patient to teach them how to self-inject the Acthar. UBC arranges for HITS, and tracks all such interactions through a database maintained for Mallinckrodt. All bills for such HITS are paid by Mallinckrodt, who is happy to provide free injection training to remove any potential obstacle to a patient taking Acthar.

174. The Acthar Start Form (Exhibit “A” hereto), by which all Acthar is prescribed, has section for the provider to request HITS for the patient.

175. These direct interactions between the Defendants and the Class give Plaintiff and the Class standing to sue on all counts. At a minimum, they raise serious fact questions about the uniqueness of Defendants’ scheme to allow this case to proceed to discovery.

C. THE ACTHAR “PRICING SCHEME”

1. Defendants raise the AWP for Acthar, and charge such prices to TPPs, without regard for the lack of proven safety, efficacy or value of the drug to treat the diseases for which they market and sell Acthar.

176. Mallinckrodt acquired the rights to Acthar from Aventis in July 2001.

177. At the time of its acquisition, the end payor price of a vial of Acthar charged to TPPs, like the Plaintiff, was approximately \$40.00.

178. After acquisition, Mallinckrodt raised the per-vial price substantially. By September 2001, Mallinckrodt raised the list price for Acthar, or the wholesale acquisition cost (“WAC”), to \$748.16. It raised the end payor price, or the average wholesale price (“AWP”), to \$935.20.

179. Like other brand name, injectable drug manufacturers, Mallinckrodt adopted a 25% markup factor for its AWP for Acthar. In other words, once Mallinckrodt sets a new WAC, the AWP is calculated at 25% above the new WAC.

180. From 2001 until Mallinckrodt executed its new strategy in 2007, the Acthar WAC grew from \$748.16 to \$1,650.23, while the AWP grew from \$935.20 to \$2,062.79 (25% higher than the WAC).

181. The below table reflects the WAC and AWP price changes (and the percentage increase) as implemented by Mallinckrodt from 2001 through February 2007, and as charged by UBC:

DATE	WAC	AWP	% INCREASE
Sept. 21, 2001	\$748.16	\$935.20	-
June 24, 2002	\$782.60	\$978.25	4.6
April 1, 2003	\$859.20	\$1,074.00	9.787
March 1, 2004	\$902.00	\$1,127.50	4.98
January 1, 2005	\$988.00	\$1,235.00	9.53
April 1, 2005	\$1,037.20	\$1,296.50	4.98
January 1, 2006	\$1,120.40	\$1,400.50	8.0
October, 1, 2006	\$1,232.44	\$1,540.55	10.0
December 21, 2006	\$1,269.41	\$1,586.76	3.0
February 2, 2007	\$1,650.23	\$2,062.79	30.0

182. The double-digit price increase in 2005 and 2006 were not enough, nor as the 30% price increase in February 2007. Mallinckrodt's greed required more.

183. When Mallinckrodt implemented its new strategy with UBC on August 27, 2007, they raised the WAC for Acthar from \$1,650.23 to \$23,269.00. They also raised the AWP for Acthar from \$2,062.79 to a staggering \$29,086.25 – representing a 1,310% increase in the span of a month, and a 72,615% increase from the time Mallinckrodt first acquired the drug.

184. Until Mallinckrodt obtained FDA approval for the IS indication in 2010, the price of Acthar remained relatively stable. However, in 2011, Mallinckrodt increased the price of Acthar three times: by 5% on January 3, 2011, by another 5% on June 1, 2011, and then by 6.5% on December 27, 2011. These three price increases totaled a staggering 16.5% in one year. As of 2012, Acthar's end payor price/AWP stood at \$34,150.00.

185. But Mallinckrodt and UBC were wary of TPP's increasing concerns about Acthar's price and lack of proven value for the various indications being promoted. A poignant example is the attempted price increase in September of 2012.

186. In September 2012, Mallinckrodt desired to take another 5% price increase. The decision to raise the Acthar price was made by Questcor's COO Steve Cartt in early September.

187. However, on September 19, 2012, health insurer Aetna, announced that it would cut back reimbursements for Acthar, due in part to the lack of evidence of Acthar efficacy for various disease states.

188. Questcor's stock plummeted 56% the same day as the Aetna announcement. Within a week, Questcor's stock had fallen another 37%.

189. Mallinckrodt scrambled to place the intended price increase "on hold for now", due to the Aetna situation. It so advised Curascript and UBC, which both agreed.

190. This price increase was later taken by the Defendants on June 7, 2013, when the Acthar WAC was increased 5% to \$30,120.00 and the Acthar AWP was increased 5% to \$37,650.

191. In 2014, Defendants resumed their aggressive price increase strategy, just prior to Mallinckrodt plc's \$5.9 billion acquisition of Questcor. But they continued to conceal the truth, lying to the public about the real reasons for the exorbitant price increases.

192. On January 16, 2014, the Acthar WAC and AWP were raised 5%, to \$31,626 and \$39,532.50, respectively.

193. Prior to Questcor's acquisition by Mallinckrodt plc in 2014, Questcor had planned an additional 5% increase for Acthar in December 2014. This would have meant a total percentage increase of 10% for the year.

194. However, after the acquisition, Mallinckrodt raised the planned increase to 8.9%, or 13.5% for the year.

195. In the interim, the Executive Committee (“EC”) of Mallinckrodt met. The EC consists of the senior management of Mallinckrodt, including President and CEO Mark Trudeau and Executive Vice President and Chief Commercial Officer Hugh O’Neill.

196. COO O’Neill raised the matter of the 8.9% price increase with the EC on Friday December 12, 2014, and it was decided by the Mallinckrodt leadership team to “change[] the magnitude” of the pricing action, reducing the proposed increase from 8.9% to 2%. The EC did this in order to take advantage of an “opportunity for breakthrough pricing strategies” in the future.

197. It is believed and therefore averred that such pricing opportunity was presented by Questcor’s prior acquisition of Synacthen, a synthetic version of ACTH.

198. Questcor had completed its acquisition of Synacthen in 2013.

199. As a result of such Synacthen acquisition, Mallinckrodt was confident that reducing the planned 8.9% Acthar price increase in late 2014 to little more than the consumer price index [which stood at about 1.7% in 2014] -- causing a \$26 million shortfall in the forecasted revenues [based on the 5% increase that was “baked in” for December] -- would not negatively affect the company moving forward. This decision, while ostensibly made against Mallinckrodt’s economic self-interest in the short term, was made to further enhance their profits in the long run.

200. Accordingly, with the direct input and hands-on decision-making by President and CEO Trudeau, Mallinckrodt reduced its December 2014 Acthar price increase to 2%. This

led to a WAC increase to \$32,260.00 and an AWP increase to \$40,325.00, respectively, on December 16, 2014.

201. Under Mallinckrodt plc's stewardship, the AWP of Acthar has continued to rise in to well above \$40,000 in 2018, when Local 420 began paying for it, despite Mallinckrodt's misrepresentations about Acthar's price.

202. In 2018, Mallinckrodt's CEO, Mark Trudeau, deliberately lied to the public in a press release. He willfully misrepresented that "[t]he current 'list price' per vial for the drug is \$36,382, not the higher numbers which have appeared in various reports, and Mallinckrodt discounts this list price to both public and private payers." *See* Mallinckrodt 2018 Statement at Exhibit "D" hereto. This statement was false, misleading and deceptive.

203. The price paid by "private payers", like Local 420 and the Class of TPPs in this case, is the AWP. As set forth above, that price has been in excess of \$40,000 since 2014. Mallinckrodt does not "discount" that price to Local 420, or any other TPP, as claimed.

204. If Mr. Trudeau was actually representing that the WAC for Acthar was \$36,382 as of June 2018, which is not the price paid by "private payers" like Local 420, then the AWP paid by private payers would have been actually a staggering \$45,477.50, based on the historical 25% markup Mallinckrodt has employed for its Acthar AWPs since the inception of its ownership in 2001.

205. Since the acquisition of Acthar in 2001, the end payor price of Acthar has grown over 100,000% reflecting the precipitous rise in the value of the Acthar assets from \$100,000 in 2001 to \$5.9 billion in 2014 – a 5,899,900% increase in value. Mallinckrodt has continued to deceive payors like Local 420 and the TPP Class about the actual prices of Acthar, and the reasons for its many staggering price increases.

206. In fact, in direct response to a lawsuit filed against Mallinckrodt in April 2017 by the City of Rockford, Illinois, Mallinckrodt issued a public statement, claiming to “set the record straight” about Acthar pricing and other issues. *See* Mallinckrodt 2018 Statement at Exhibit “D” hereto. This press release is replete with misrepresentations and deliberate falsehoods that only continues to deceive Local 420 and the Class about Acthar pricing and the actual reasons for the high Acthar prices.

207. The 2018 press release was issued by the company CEO Mark Trudeau who falsely, misleadingly and deceptively claimed that the “price of H.P. Acthar Gel today is \$38,892, before discounts provided to payers.” *Id.*

208. However, when Local 420 paid for Acthar in 2018, the Acthar AWP was well over \$40,000.00. In fact, the AWP for Acthar had been raised by Mallinckrodt to \$40,325.00 on December 16, 2014, 4 years before Trudeau willfully made his materially false statement about Acthar pricing.

209. Today, the price of Acthar stands at over \$43,000.

210. Mallinckrodt has conspired and agreed with UBC, and others, to conduct a fraudulent scheme and conspiracy to deliberately inflate the AWP for Acthar, to maintain such high AWP for Acthar in the face of complaints by patients and TPPs, like Local 420, to communicate such inflated prices, and to circumvent patient and payor concerns about Acthar’s high prices through the Distribution and Marketing Schemes alleged herein. As Defendants well know, the AWP is used by both government and private assistance programs for prescription drug reimbursement.

211. Government and private assistance programs, like those of Local 420 and the Class, have used the AWP published in pharmaceutical industry publications, such as the Red Book and Medispan, for years as a basis for reimbursement, in whole or in part.

212. These publications set forth the false AWP for Acthar, as reported with each price change by Mallinckrodt. In periodically announcing the AWP for Acthar, the publications simply published the prices supplied to them by Mallinckrodt. Mallinckrodt knew that it could, and did directly, control and raise the AWP for Acthar at any time simply by forwarding to the pricing compendia a new and higher AWP.

213. This Pricing Scheme allowed Mallinckrodt to control, in conjunction with its Distribution and Marketing Schemes, its profit levels, and the profits of its HUB, UBC, by the direct manipulation and reporting of the Acthar AWP.

214. Years before Mallinckrodt and UBC engaged in their Pricing Scheme to manipulate the Acthar AWP to increase their profits, in 2003, the Office of Inspector General (“OIG”) admonished, “[i]f a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated.” *In re Pharm. Ind. Average Wholesale Price Litig.*, 491 F.Supp. 2d 20, 39-44 (D. Mass. 2007). Ironically, this published decision appeared the same month in 2007 that Mallinckrodt and UBC signed their first of many conspiratorial agreements to manipulate and communicate the AWP for Acthar.

215. Plaintiff is not alone in its charge of deceptive conduct against Mallinckrodt. In April 2015, Mallinckrodt settled a securities fraud class action brought by its investors against the company in January 2013 in the United States District Court for the Central District of California for the sum of \$38 million. The securities lawsuit charged the company with, inter

alia, “issu(ing) false and misleading statements about the effectiveness of, and prospects for, Questcor’s sole product, Acthar.” The court denied in part the Defendants’ motions to dismiss, allowing certain claims to proceed. The court then granted class certification in November 2014.

216. Following the settlement, Mallinckrodt’s CEO Mark Trudeau suggested to investors on October 6, 2015 that drug prices “should be reflective of the value that you deliver to the marketplace.”

217. However, following this settlement, and the filing of the Rockford lawsuit, leading executives at PBM Express Scripts (which owned UBC) conceded that Acthar is not worth what Mallinckrodt is charging for it, and what TPPs like Local 420 and IUOE Local 542 have been paying for it, especially for the treatment of MS, NS and RA. Despite this, neither Mallinckrodt nor UBC have changed their ways.

2. The Views of Express Scripts’ Senior Management On the Lack of Acthar “Value” for the Prices Charged.

218. When Mallinckrodt chose to increase the price of this 50-plus year-old medication, the leading PBM, Express Scripts, did not push back. This likely due to its ownership of Curascript and UBC, which were both subsidiaries of Express Scripts at the time.

219. However, when confronted about the 2007 price increase in later years, Express Scripts’ Chief Medical Officer Steve Miller stated that “[t]he increase was a manufacturing decision. I can’t comment on it.”⁵

220. On May 19, 2017, just weeks after Mallinckrodt was sued by the City of Rockford in early April 2017 for, inter alia, price fixing, Express Scripts senior officers made comments about the “somewhat controversial” drug Acthar on a private investor conference call hosted by

⁵ *Freudenheim, supra.*

Citi.6 The Citi interviewer stated, “it’s been in the news as – given the pricing around the drug over the past – I don’t know – 12 months at least,” and then asked for “any thoughts around ... how that can be managed and how you see cost of the playing out?” Citi Transcript at 12.

221. In response, Express Scripts’ Senior Vice President, Supply Chain and Specialty Pharma, Everett Neville stated:

I don’t think [Acthar is] a very great [drug] – *it’s a pretty poor drug with a very limited need* and certainly [Express Scripts Chief Medical Officer, Dr.] Steve [Miller] could comment. He’s a doctor and I’m just a really bad pharmacist.

...[Y]ou know, and Steve, you could chime in here too, but I think Steve and I both would agree, and *I think everybody in our company would agree, that the product is vastly overpriced for the value. We don’t set the price.* We’ve told [Mallinckrodt] that. I personally told [Mallinckrodt’s] management team that their drug is hugely overpriced. I know Steve has as well.

Citi Transcript at 12 (emphasis added) (brackets added).

222. Dr. Miller stated that he was in “100% agreement with [Mr.](Everett).” Citi Transcript at 12 (brackets added). He added, “[i]f you look at the data, the indications for the drug are really – while it had, in the compendium, it’s listed under a lot of indications, its real use should be very, very limited. It’s an old drug. There’s better products in the marketplace...”. Citi Transcript at 12-13.

223. One of the areas where Acthar should be limited is the treatment of rheumatic disorders, like the condition suffered by the beneficiary of Local 420.

⁶ See Conference Call Transcript of call hosted by the Citigroup Healthcare Team on May 19, 2017 at 11:00a.m. est, with Dr. Steve Miller, Chief Medical Officer from Express Scripts, and Mr. Everett Neville, Senior Vice President of Supply Chain and Specialty (“*Citi Transcript*”).

224. Indeed, in December 21, 2017, Express Scripts provided an updated “Prior Authorization Policy” for Acthar, effective January 2018 (hereinafter “2018 Prior Authorization Policy”).

225. The 2018 Prior Authorization Policy admitted that Acthar “may be used for ... rheumatic disorders as an adjunctive therapy for short-term administration for an acute episode or exacerbation (in psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis [selected cases may require low-dose maintenance therapy]...”.

226. The adult beneficiary of Local 420 was prescribed Acthar for a rheumatic disorder, but not for an RA exacerbation and not in low-dose form, as required.

3. Mallinckrodt Acquires Acthar from Aventis at a Low Price Reflective of its Lack of Market Value.

227. In 2001, Mallinckrodt, then Questcor, acquired Acthar from Aventis Pharmaceutical Products, Inc. (“Aventis”) for only \$100,000. This low price was reflective of the lack of market value for Acthar for the treatment of disease.

228. But in 2014, seven years after Questcor embarked on its “new strategy” for Acthar, Mallinckrodt acquired Questcor for approximately \$5.9 billion.

229. In the July 27, 2001 Asset Purchase Agreement between Aventis and Questcor, Questcor acknowledged that there were risks in the transaction due to the limited approved indications for Acthar. Indeed, Questcor and Aventis held a meeting with FDA on February 7, 2001 in which such issues were discussed. Nevertheless, Questcor went through with the purchase.

230. Acthar’s value was limited because it was the “gold standard” for treating only one condition, IS. IS is a serious condition in infants, but one with an annual patient population of less than 2,000 children per year. However, Acthar was not originally approved by the FDA to

treat IS, further limiting its value. As described above, the IS indication was not approved by the FDA until 2010. Between 2001 and 2010, IS was an *off-label indication* which Mallinckrodt actively marketed.

231. Between 2001 and 2007, Acthar's primary sales were for the treatment of IS, despite its off-label indication.

232. Consequently, because Mallinckrodt's primary business concerned the off-label marketing and sales of Acthar for IS, it is not surprising that it sought to expand upon such business model in other off label areas, once the IS indication was approved.

233. After the "new strategy" was adopted, Mallinckrodt expanded its marketing for other unapproved uses and doses in MS, NS, SLE and RA. As a result, sales expanded exponentially in these areas, expanding the profits of the company, all due to Mallinckrodt's company-wide campaign of off label promotion.

234. It was only because of the profits achieved in the areas other than IS that Questcor was deemed worth nearly \$6 billion to Mallinckrodt. Consequently, Mallinckrodt has continued to advance the distribution, pricing, marketing and sales schemes initiated by Questcor. These are not "legacy" matters, as Mallinckrodt has falsely claimed. Instead, they have been engrained in Mallinckrodt's business and corporate culture since the early 2000s.

235. For that reason, Local 420 and the Class seek declaratory and injunctive relief against Mallinckrodt to put an end to the ongoing schemes for the benefit and future protection of patients and private TPPs, regardless of whether the federal government chooses to settle with Mallinckrodt. The putative Class described below expressly excludes government payors who have settled with Mallinckrodt.

D. THE ACTHAR “MARKETING SCHEME”.

236. The Marketing Scheme in this case is identical to the scheme alleged in the Strunck & Pratta and Clark Complaints, and as amended in the U.S. Complaint in Intervention all filed and pending in this Court. The only difference is the affected class of plaintiffs – all private payors as opposed to the government payors in the government’s case.

237. To duplicate those factual averments would exponentially and unnecessarily grow the length of this already lengthy Complaint.

238. Nevertheless, Local 420 summarizes those averments herein to make clear that it and the Class of TPPs it seeks to represent suffered harm as a result such Marketing Scheme.

1. As Part of its “New Strategy”, Mallinckrodt Creates a Team of Highly-Trained “Medical Sciences Liaisons” to Promote the Sale of Acthar at High Prices Through a Campaign of Misrepresentations and Deception in Conjunction with KOLs.

239. As part of the new strategy in 2007, Mallinckrodt created a new position within the company: “Medical Science Liaison” or “MSL” were highly trained sales employees who were deployed to speak directly to doctors about the safety and efficacy of Acthar for unapproved uses and doses.

240. Mallinckrodt also employed MSLs to provide periodic training to employees of UBC.

241. Such training included information about Acthar’s approval uses and doses, as well as its purported safety and efficacy for unapproved uses and doses based upon Mallinckrodt-sponsored “open label” clinical studies, usually conducted by Mallinckrodt-paid KOLs.

242. In the Strunck & Pratta Complaint, they detail the important role the new MSLs played in the Mallinckrodt and UBC schemes alleged. Specifically, the allege:

Another tactic employed by Questcor to promote H.P. Acthar Gel off-label is to use its Medical Science Liaisons (“MSLs”) as an end-run around sales representatives’ duty to lawfully promote the drug. Questcor’s use of MSLs in this manner is a way for the company to make the unlawful promotional activities for H.P. Acthar Gel appear lawful. *See e.g.* 21 C.F.R. 99.101. et seq.

Medical Science Liaisons are supposed to talk with physicians only about science-to-science issues, and only when those discussions are initiated by the physician. Their primary role is to engage in non-promotional medical activities, and they are not supposed to engage in product promotion. Thus, a sales representative is not permitted to use an MSL as a conduit through which to initiate and pursue off-label promotion activities with physicians.

The law notwithstanding, Questcor erects no wall between its medical and sales staffs, and actively encourages its MSLs to probatively participate in promotional activities. Medical Science Liaisons routinely accompany Questcor sales representatives on their sales calls.

Questcor encourages its sales representatives to probatively partner with MSLs to increase H.P. Acthar Sales growth. Commonly, the sales representative will initiate an off-label discussion, and then the MSL will complete the discussion. On other occasions, sales representatives ask their MSL colleagues to contact physicians who are reluctant to prescribe H.P. Acthar Gel for off-label uses in order to attempt to overcome that reluctance whether or not the physician initiated the off-label discussion or requested further information. Again, Questcor ignores that MSLs are not permitted to engage in promotional activities.

Strunck & Pratta Complaint at ¶¶ 142-145.

243. The Relators then proceed to explain the critical role of these MSLs in promoting the off-label use of Acthar, especially for the unapproved, in effective and harmful 5-day dose prescribed to MS patients, like the patients of IUOE Local 542 described below. The specifically allege as follows:

Five Day Course of Treatment Was Ineffective and Harmful to Patients

Many physicians have rightfully rejected Questcor’s efforts because the 5-day protocol is not supported by any credible evidence, and because experimenting with it cannot be justified in light of its cost and potential for patient harm. However, many physicians have been persuaded to

switch from Solu-Medrol to a 5-day course of treatment with H.P. Acthar Gel – in large measure due to the valuable inducements provide to them by Questcor, as described herein.

In Relator Strunck's experience, approximately half the doctors he persuaded to prescribe H.P. Acthar Gel for a five-day course of treatment had to order repeat prescriptions in as few as two to three months due to patient relapse, even though patients treated with Solu-Medrol typically relapse only after twelve to eighteen months. Relator Strunck knows this issue was widespread, because it was regularly was [sic] discussed during regional sales team conference calls. In Relator Pratta's experience, she experienced the same reactions from patients who doctors use the five day [sic] course of treatment.

Questcor's decision to promote H.P. Acthar Gel only for a five-day course of treatment came at the detriment of patients and patient safety. The issue was routinely discussed during regional sales calls and national sales meeting, Questcor knew that although a typical patient treated with Solu-Medrol for five days would relapse in twelve to eighteen months, and that a typical patient treated with H.P. Acthar Gel would relapse in as few as two to three months.

Thus, the cost to treat a typical patient with Solu-Medrol would be less than \$5,000 over a five-year period (approximately four treatment cycles), but the cost to treat the same patient with H.P. Acthar Gel would be almost \$700,000 (approximately 30 treatment cycles). As an example, at the Regional Sales Meetings on March 7th-8th in 2013, held in New Brunswick, New Jersey Blainy Creasy, the region's new Medical Science Liaison (MSL) gave a scientific talk about Acthar and its new mechanism of action (MOA) and how they intend to position it in the physician's offices. Stacy Clancy said that *"even though we sell 5 day, the docs are finding out that it is not working and some patients need another vial."*

Plainly, promoting a five-day course of treatment with H.P. Acthar Gel inured to the patient's financial detriment and, more importantly, to the detriment of the patient's health and well-being. Questcor promoted the five-day treatment cycle in order to get both the physician and the patient "hooked" on the substantially more expensive H.P. Acthar Gel in lieu of Solu medrol [sic].

Strunck & Pratta Complaint at ¶¶ 146-150.

2. Mallinckrodt Uses KOLs to Create Biased Clinical Data to Deceive Patients and TPPs, and to Cultivate High Acthar Prescribers as “Spokes-Doctors”.

244. In view of the extremely limited clinical data that existed at the time of Acthar’s approval in 1952, and since that time, Mallinckrodt has been forced to try to create data to support its false and misleading marketing effort about Acthar’s “value” to treat disease beyond the narrow indications on its label.

245. Mallinckrodt cultivated so-called “Key Opinion Leaders” or “KOL’s” create such data, and then disseminated such data to other doctors through their highly-compensated spokes-doctors.

246. As ProPublica has reported, and as demonstrated below by a few examples, dozens of high prescribers of Acthar have been cultivated as spokes-doctors and paid tens of thousands of dollars for their work on behalf of Mallinckrodt in this regard.

247. These KOLs are paid by Mallinckrodt to cultivate a narrow group of high prescribers of Acthar, some of whom are also engaged by Mallinckrodt to generate clinical data based on their own patient populations to support Acthar’s off-label uses and doses, without FDA oversight, input or scrutiny. The company then widely disseminates the results of such anecdotal studies as part of its vast marketing campaign to convince doctors that Acthar is safe and effective for unapproved uses.

248. As similarly alleged in the opioid litigation, in which Mallinckrodt has been sued as a defendant in MDL 2804 (pending in an Ohio Federal District Court) and in state courts throughout the country, including Pennsylvania, Mallinckrodt cultivated a select circle of doctors who were chosen and sponsored for their pro-Acthar messages in order to create “the grave misperception science and legitimate medical professionals favored the wider and broader use”

of Acthar. These KOLs were used to present the appearance that unbiased and reliable medical research supporting the broad use of Acthar for neurology, nephrology and rheumatology had been conducted and was being reported on by independent professionals. *See In re: National Prescription Opiate Litigation*, Case No. 1:17-md-02804-DAP, N.D.Ohio, Doc. No. 1025 (Report and Recommendation dated October 5, 2018) at 6-7.

249. The publications of many of these physicians, including those of Dr. James James A. Tumlin of Tennessee described below, were funded by Mallinckrodt as they supported the position that Acthar for broad use in neurology, nephrology and rheumatology was appropriate, all the while knowing these statements were false, misleading and deceptive.

250. Mallinckrodt utilized KOLs, like Dr. Tumlin, to develop “open label” clinical data to support Mallinckrodt’s promotion of Acthar for new indications in nephrology, neurology and rheumatology.

251. “Open label” clinical trials, unlike the FDA-approved trials described above, do not attempt to disguise the drug being studied, meaning that no standard treatment or placebo is utilized. This leans towards bias, as both the patient and the physician are aware of which groups are receiving what type of treatment. The results are thus unreliable.

252. In NS, for instance, Mallinckrodt was aware as early as 2009 that doctors were nearly unanimous in their expression of a need for clinical data to support the efficiency and safety of Acthar in NS, as well as the need for clarification on the appropriate dosing regimen. Working with KOLs who expressed interest in generating such data became a major focus for Mallinckrodt MSLs in 2009 and beyond.

3. JAMA Study of Mallinckrodt KOLs, and Connection Between Kickbacks Payments and Higher Acthar Prescriptions.

253. In June of 2018, a team of researchers and concerned clinicians used Medicare and Medicaid data to investigate the frequency of use and overall expense of Acthar. To characterize payments from Mallinckrodt to physicians who prescribe Acthar, these researchers and clinicians conducted a cross-sectional analysis of data from CMS, including the Medicare Part D Public Use Files. Focusing on 2015, the researchers used the database to identify physicians, and their specialties, who prescribed Acthar more than 10 times that year, characterizing them as “frequent prescribers.”

254. Their study, published in JAMA Network Open, found that in 2015 only 300 providers wrote more than 10 prescriptions for Acthar. Of those 300 prescribing providers of Acthar, 235 of them were rheumatologists, neurologists, or nephrologists.

255. Further, among those 235 rheumatologists, nephrologists and neurologists who issued more than 10 prescriptions for Acthar in 2015, 88% (207/235) received payments from Mallinckrodt – with more than 20% of those frequent prescribers receiving more than \$10,000 – despite Acthar’s considerable cost and the dearth of evidence to support its use.

256. Some physicians prescribing Acthar were paid as much as \$56,000-\$138,000 by Mallinckrodt for activities related to Acthar, making such payments equivalent to the salary of full-time employees of Mallinckrodt.

257. Indeed, as noted by one of the researchers and clinicians in the JAMA study, Dr. Daniel M. Hartung, “[e]xpensive therapies with uncertain or insufficient evidence supporting their use should be particularly scrutinized.” He further noted that, “[t]he continued growth in corticotropin [Acthar] use is peculiar given its very high cost, widespread negative media coverage, and notable lack of evidence supporting its use over lower-cost synthetic

corticosteroids. Our experience suggests aggressive marketing of the drug partly accounts for increasing use.”

258. The JAMA study also noted an association between providers who received higher compensation and their writing more Acthar prescriptions—and the Acthar prescriptions written by these frequent prescribers accounted for \$200 million in Medicare spending during the period that the study examined.

259. Indeed, this study also found that from 2011 to 2015, spending on Acthar increased ten-fold, totaling more than \$1.3 billion for just several thousand Medicare patients. Upon information and belief, and given the continued marketing of Acthar by Mallinckrodt pursuant to the marketing scheme alleged by the Qui Tam Relators, those numbers have increased since 2015.

260. The conclusion of the JAMA study was that most nephrologists, neurologists, and rheumatologists who frequently prescribe Acthar received Acthar-related payments from Mallinckrodt, suggesting that financial conflicts of interest may be driving the prescription and use of Acthar. Indeed, as noted by Dr. Hartung, “we observed a positive association between the amount of money paid to these prescribers, their prescribing intensity, and corticotropin [Acthar] expenditures in the Medicare program with a return on investment for Mallinckrodt of about 5:1.”

261. Consistent with the JAMA study’s conclusions, in October of 2014, Mallinckrodt had a briefing with its investors. At that briefing, Dr. Gary Phillips, the Senior Vice President, and President of Mallinckrodt's Autoimmune and Rare Disease Business, pledged, “[t]he one thing that you can be sure of is that the awareness and the evidence of the product will just expand dramatically over the next year.”

262. Dr. Phillips presented PowerPoint slides detailing the company's strategy, including the need to get Acthar to its "underserved patient population" in rheumatology, pulmonology, ophthalmology, dermatology and kidney disease.

263. One graphic showed 9,000 patients were currently being treated with Acthar and that 300,000 people had "addressable but currently untreated" conditions. The slide also noted a total of 4 million Americans suffered from "Acthar indicated conditions."

264. The aggressive marketing push outlined by Mallinckrodt executives in that October 2014 investor meeting appears to have paid off: Medicare spent more than \$600 million on more than 12,000 Acthar claims in 2016 – more than double the numbers from 2013, the year before Mallinckrodt's purchase of Questcor. Many of those prescriptions were made by rheumatologists, nephrologists, and neurologists – the very type of doctors Mallinckrodt executives said they planned to target in October 2014 to capture the "underserved patient population."

265. In 2018, Local 420 began paying for Acthar prescriptions for the wife of one of its members for the treatment of a rheumatic disorder which as identified by Mallinckrodt as an "underserved" area.

266. Few medical providers have come forth to blow the whistle on Mallinckrodt's tactics. One brave doctor, Dr. Megan Clowse of the Duke University School of Medicine, wrote last year that "[w]e also know from personal experience that Acthar's manufacturer is actively looking for clinical researchers open to perform more, small, open-label, nonrandomized trials of their drugs." In other words, even doctors not receptive to Mallinckrodt's marketing scheme are approached. Discovery of Mallinckrodt's records will enable Plaintiff and the Class to ferret out the chaff from the wheat, the ethical doctors from the spokes-doctors.

267. One such spokes-doctor, Dr. William Shaffer, a neurologist in Greeley, Colorado, was the highest prescriber of Acthar in 2012. He wrote only 78 prescriptions for the drug, but the prescribed Acthar cost Medicare \$4,000,000.

268. Dr. Shaffer has been paid handsomely by Mallinckrodt for his loyalty to the company. The very next year, Dr. Shaffer was rewarded by being engaged by Mallinckrodt to speak as a KOL on multiple occasions, in multiple places, as part of all-expense paid trips sponsored by the company. For instance, he was flown to the east coast to conduct four speaking engagements with dozens of the doctors over the course of two days, January 24-25, 2013. He spoke in Reston and Falls Church, Virginia, and then Bethesda, Maryland.

269. But Dr. Shaffer was far from alone. He is just one of dozens of highly-compensated Mallinckrodt spokes-doctors, all important spokes in the wheel of Mallinckrodt's RICO conspiracy, as they are all connected to Mallinckrodt's self-described "HUB" and all profit as integral "spokes" in Mallinckrodt's marketing and sales scheme.

4. Leading "KOLs" for Mallinckrodt Promote for "New Indications" through a Scheme of "White Coat Marketing".

270. Mallinckrodt sought help in effectuating their scheme and conspiracy by seeking KOLs in the medical fields where Acthar was not the preferred course of treatment. Indeed, Acthar was not approved by the FDA for the long-term treatment of any disease; instead, Acthar has had a narrow indication since 1952 for the treatment of only acute exacerbations of disease and flare-ups.

271. As Express Scripts' 2018 Prior Authorization Policy acknowledged, "data and guidelines do not suggest that Acthar has a substantial role in therapy" for most of the diseases for which Mallinckrodt promotes and sells Acthar. Instead, Express Scripts found in late 2017,

as the FDA found in 2010, that “[f]urther data are needed before use in other areas [beyond IS and MS] can be recommended.” *Id.* at 4 (brackets added).

272. To overcome this lack of data to support to use of Acthar to treat “new indications”, and to support its off-label marketing effort, Mallinckrodt engaged KOLs strategically situated throughout the country, initially to determine whether there was a viable potential market for Acthar with neurologists, nephrologists and rheumatologists.

273. In order to cultivate KOLs for its white coat marketing scheme, Mallinckrodt directed its sales force call on select neurologists, nephrologists and rheumatologists to discuss the treatment of new indications of disease with leading practitioners in these fields, and to begin developing and sharing the data on treatment with Acthar.

274. Mallinckrodt then began “[w]orking with KOLs who have expressed interest in generating such data” to support the off-label use of Acthar to treat such “new indications”. This became a “major focus” for Mallinckrodt after it acquired Questcor.

275. This new marketing initiative into off-label promotion of Acthar for “new indications” was made possible by the “success of the new Acthar pricing strategy” by which “significant funds [were] now available for the first time to support Acthar-related research” by paying “KOLs to explore areas of mutual research interest.” *Id.* In other words, the profits realized by the implementation of the “new strategy” in 2007 for IS treatments made it possible for Mallinckrodt to pay doctors to serve as KOLs as part of the Mallinckrodt white coat marketing strategy into rheumatology, nephrology and other areas.

276. The practice of “white coat marketing” was identified by the Office of Inspector General (OIG) of the federal government as a potential area of fraud and abuse as early as 1991.

See, e.g., OIG Advisory Opinion No. 11-08, issued June 12, 2011, at 6 (citing 56 Fed. Reg. 35952, 35974 (July 29, 1991)). As described in Advisory Opinion No. 11-08:

The fraud and abuse risks are compounded where, as here, a physician or other health care professional is involved in the marketing activity – a practice sometimes referred to as “white coat” marketing. White coat marketing is closely scrutinized under the anti-kickback statute because physicians and other health care professionals are in an exceptional position of public trust and thus may exert undue influence when recommending health care-related items or services – especially when marketing to their patients. See, e.g., 56 Fed. Reg. 35952, 35974 (July 29, 1991). Given the nature of these relationships, when physicians or other health care professionals market items and services to their patients, patients may have difficulty distinguishing between professional medical advice and a commercial sales pitch.

5. Mallinckrodt KOLs Working for Mallinckrodt as Spokes-Doctors in Pennsylvania and Throughout the Country.

277. While it is impossible without the benefit of discovery to identify and describe the full nature and extent of Mallinckrodt’s unlawful white coat marketing scheme for the off-label promotion of Acthar – as only discovery will reveal the facts that lie within Mallinckrodt’s exclusive custody and control – specific examples demonstrate that the scheme was widespread in Pennsylvania and elsewhere.

a. Dr. David R. Mandel in Chardon, Ohio

278. Dr. David R. Mandel (“Dr. Mandel”), is a rheumatologist with offices located at 320 Center Street, Chardon, Ohio.

279. Public reports reveal that Dr. Mandel was regarded as a top prescriber of Acthar making up 1% of all prescriptions with 14 patients receiving Acthar.

280. According to the website sponsored by Propublica,⁷ Mallinckrodt claims Dr. Mandel was only paid the following disclosed sums for his promotional activity on behalf of Mallinckrodt in selling Acthar to other doctors throughout the country:

Aug. 2013 - Dec. 2013	\$16,653
Jan. 2014 - Dec. 2014	\$3,077
Jan. 2015 – Dec. 2015	\$3,032
Jan. 2016 – Dec. 2016	\$126

281. However, in 2014, Dr. Mandel pled guilty and was sentenced to probation and paid \$650,000 for causing the shipment of “misbranded” drugs.

282. Mallinckrodt has been sued by a former employee, Barry Franks. In Franks’ Complaint, he details the unlawful conduct of Dr. Mandel, along with another Mallinckrodt sales representative, identified as “Smith”. It is believed and therefore averred that “Smith” is actually Christopher Sender, the Mallinckrodt sales manager in charge of the Ohio area where Dr. Mandel practices.

283. As a highly compensated KOL and spokes-doctor for Mallinckrodt, Dr. Mandel actively promoted the sale of Acthar to patients and TPPs for unapproved uses and doses in order to get TPPs, like Plaintiff and the Class, to pay for Acthar at inflated prices. Specifically, Dr. Mandel promoted the sale of Acthar for RA.

⁷ See <https://projects.propublica.org/docdollars/> According to Propublica, “[p]harmaceutical and medical device companies are required by law to release details of their payments to a variety of doctors and U.S. teaching hospitals for promotional talks, research and consulting, among other categories. Use this tool to search for general payments (excluding research and ownership interests) made from August 2013 to December 2016.”

284. In promoting Acthar for unapproved uses and doses in the treatment of RA, Dr. Mandel misrepresented and deceived patients and payors about the Acthar MOA and the limited FDA approval.

285. Dr. Mandel specifically wrote to payors, after his initial prescriptions for Acthar were denied due to the prior authorization TPPs had placed on Acthar to prevent high payments for specialty drugs, especially for off label indications. Working with Mallinckrodt's HUB, UBC, however, Dr. Mandel sent letters appealing the TPP's denial decisions. Such letters were sent to UBC, to be used with TPP's, through use of the mail, including email, and wires. They contained false and misleading statements about the limited FDA approval of Acthar and its purported MOA.

286. Specifically, as to the FDA approval, Dr. Mandel would write to TPPs that Acthar was approved for specific RA indications, when it was not. As for the Acthar MOA, Dr. Mandel would write to TPPs misrepresenting that the Acthar MOs was known, when it was not. Indeed, he would provide lengthy explanations about the Acthar MOA, which explanations were not based upon any FDA approval or any FDA approved clinical studies.

287. The letters sent and other communications had between Dr. Mandel and TPPs in order to appeal the denial of Acthar were vetted by and shared with Mallinckrodt and UBC. Mallinckrodt and UBC were fully aware of Dr. Mandel's misrepresentations, and yet took no steps to stop or correct them, to the detriment of the TPPs who paid for the Acthar based upon such misrepresentations. Instead, Mallinckrodt rewarded Dr. Mandel with increasing KOL speaking engagements, for which he was well compensated.

288. Based upon the JAMA study and other evidence of Mallinckrodt's KOL program for Acthar, including the above-described example of Dr. Mandel for which specific evidence is

available, it is averred that other KOLs conducted themselves in the same manner. That is, Mallinckrodt-paid KOLs misrepresented and deceived TPPs about the MOA for Acthar and the limits of its FDA approval, in order to get TPPs to pay for Acthar for unapproved uses and doses. These false and misleading communications were routed to TPPs through UBC via facsimile.

289. Plaintiff and the Class were harmed by such conduct, either directly through the promotional effort of Mallinckrodt KOLs and MSLs, or indirectly through their intercession in the care of beneficiaries of Plaintiff and the Class through the ASAP program and otherwise.

290. Plaintiff and other clients of the Plaintiff's counsel, along with unnamed members of the Class paid the inflated prices for Acthar for indications in MS, NS, SLE and RA pursuant to the fraudulent pricing, marketing and sales scheme alleged.

291. **MANDEL PROSECUTION FOR MISBRANDING**

b. Dr. James Tumlin in Chattanooga, Tennessee and Acument's Inflated Payments for Acthar

292. In a related case filed in Tennessee state court by the same undersigned Plaintiff's counsel, the plaintiff there, Acument Global Technologies, Inc. ("Acument") has specifically pled that Mallinckrodt hired Dr. James A. Tumlin, M.D. ("Dr. Tumlin") as a leading KOL to develop supporting data using his existing patients as test subjects in a non-FDA-approved, open label clinical study.

293. Mallinckrodt also paid Dr. Tumlin to travel the country, instructing other doctors on the unapproved uses of Acthar for nephrology and soliciting such doctors to become KOLs for Mallinckrodt.

294. Mallinckrodt has paid Dr. Tumlin handsomely for such work on behalf of the company. He has been paid hundreds of thousands of dollars.

295. Dr. Tumlin is a physician who specializes in nephrology and is associated with Nephrology Associates of Chattanooga located at 2300 E. 3rd Street, Chattanooga, Tennessee. He is founder and medical director of Southeast Renal Research Institute (SERRI) since 2005. The institute was brought to Chattanooga in 2008 and merged with Nephrology Associates' Research Department.

296. As with its other KOLs, Mallinckrodt contracted with Dr. Tumlin to conduct clinical studies of his patients using Acthar to treat their NS. This engagement was not to conduct any FDA-approved clinical study. Instead, it was intended by Mallinckrodt to pay Dr. Tumlin to conduct clinical studies of his own patients by prescribing Acthar to them for unapproved uses and doses to treat their nephrotic syndrome in order to learn about the effects of Acthar on their disease and assist Mallinckrodt in developing anecdotal clinical data with which to promote Acthar's use to other nephrologists. It is believed that one such patient was a beneficiary of Acument.

297. The 2009 contracted study was titled "A Randomized, Placebo-Controlled, Parallel-Group, Double-Blind Study of H.P. Acthar Gel (Acthar) in Treatment-Resistant Subjects with Persistent Proteinuria and Nephrotic Syndrome Due to Idiopathic Membranous Nephropathy (iMN)" (hereinafter, "Tumlin 2009 Randomized Study"). It is believed and therefore averred that Dr. Tumlin "enrolled" 15 patients for this study. While Acument's beneficiary had iMN, it is unknown whether Acument's beneficiary was included among the 15 patients Dr. Tumlin treated with Acthar as part of this contracted study. Only discovery in these cases will reveal the truth.

298. However, it is known Dr. Tumlin did not charge either the beneficiary or Acument for the Acthar he prescribed in 2011. Instead, it is believed and therefore averred that

Mallinckrodt provided the drug for free in order that Dr. Tumlin could develop data to assist in its marketing and sales of Acthar to other nephrologists.

299. Dr. Tumlin's work on behalf of Mallinckrodt became a centerpiece of its marketing plan for nephrologists, not just in Tennessee, where Dr. Tumlin's practice, Southeast Renal Research Institute, was located in Chattanooga, but throughout the country, including Pennsylvania.

300. As with other KOLs, Dr. Tumlin travelled across the country on all expenses paid trips funded by Mallinckrodt to promote the use of Acthar for NS and other disease states for which there were no clinical studies to support the treatment. Instead, Dr. Tumlin cited to other doctors his own anecdotal experience with his patients, about which he published in two papers, the Tumlin 2001 Study and the Tumlin 2013 Pilot Study.

301. While it is not yet known the total dollars Mallinckrodt paid Dr. Tumlin for these two "studies" which led to published articles, those monies were only part of Dr. Tumlin's compensation for working for Mallinckrodt.

302. For instance, Dr. Tumlin conducted a third study titled "Safety and Efficacy of Acthar Gel on Albuminuria and Urinary Transforming Growth Factor Excretion in Type II Insulin Requiring Diabetics with Nephrotic Range Proteinuria: A Pilot Study". Mallinckrodt paid Dr. Tumlin for that study.

303. In its prior authorization update released in 2018 – 9 years after Mallinckrodt began white coat marketing of Acthar through KOLs like Drs. Mandel and Tumlin– Express Scripts stated that Acthar should not have been "recommended for approval" by any doctor, including Dr. Tumlin, for treatment of iMN in patients.

304. In fact, Express Scripts cited Dr. Tumlin’s 2 published papers sponsored and paid for by Mallinckrodt: the Tumlin 2011 Study and the Tumlin 2013 Pilot Study,⁸ in concluding that “very limited data in nephrotic syndrome have studied the use of Acthar, in patients with diagnoses including idiopathic membranous nephropathy (iMN)...”.

305. Mallinckrodt MSLs and sales representatives used Dr. Tumlin’s open label studies to promote the sale of Acthar for off-label uses and doses. Similarly, UBC was trained with Dr. Tumlin’s studies and used them in discussing the use of Acthar for unapproved uses and doses with patients, providers and TPPs.

306. According to the website sponsored by Propublica,⁹ Dr. Tumlin was paid by Mallinckrodt at least the following disclosed sums for his promotional activity on behalf of Mallinckrodt in selling Acthar to other doctors throughout the country, apart from the monies he has earned conducting “clinical studies” of his patients:

Aug. 2013 - Dec. 2013	\$15,318
Jan. 2014 - Dec. 2014	\$27,733
Jan. 2015 – Dec. 2015	\$28,839
Jan. 2016 – Dec. 2016	\$50,840

⁸ Bomback AS, Tumlin JA, Baranaski J, et al. Treatment of nephrotic syndrome with adrenocorticotrophic hormone (ACTH) gel. *Drug Des Devel Ther.* 2011; 5:147-153 (“Tumlin 2011 Study”).

⁹ See <https://projects.propublica.org/docdollars/> According to Propublica, “[p]harmaceutical and medical device companies are required by law to release details of their payments to a variety of doctors and U.S. teaching hospitals for promotional talks, research and consulting, among other categories. Use this tool to search for general payments (excluding research and ownership interests) made from August 2013 to December 2016.”

307. On multiple occasions, Dr. Tumlin was paid twice by Mallinckrodt for the same services and reimbursements, in an obvious effort to overpay Dr. Tumlin for his “consulting” activities.

308. For instance, on May 23, 2016, Propublica reports that Dr. Tumlin received two payments from Mallinckrodt for “promotional speaking” in the amount of \$3,400 each. He also received two equal payments of \$2,050 for “promotional speaking” July 2, 2015.

309. On June 17, 2015, Mallinckrodt paid Dr. Tumlin the following sums for “travel and lodging” for just one day: \$537, \$529, \$393, \$393, \$276, \$87, \$50, \$50, \$30, \$30 and \$22.

310. Based on the Propublica information, it is believed that Dr. Tumlin travelled the country for Mallinckrodt to promote Acthar use in nephrology. Mallinckrodt paid with substantial “honoraria” paid, totaling up to \$5,000 at time, for his time and effort.

311. The specific dates, locations and payments relating to these Dr. Tumlin’s consulting for Mallinckrodt as a leading KOL lies within the exclusive control of Mallinckrodt and Dr. Tumlin, who have a joint interest in concealing the details of their relationship. Only discovery will reveal these details to Plaintiff and the Class.

c. Dr. Gary Clauser in Allentown, Pennsylvania And IUOE Local 542’s Inflated Payments for Acthar

312. Gary Clauser, M.D. is a board-certified neurology specialist in the Lehigh Valley Physician Group (LVPG) with offices located at 1250 S. Cedar Crest Boulevard, Suite 405, Allentown, Pennsylvania. LVPG has additional offices located in Bethlehem and Palmer Township, Pennsylvania.

313. In July 2011, Dr. Clauser treated a patient covered by the International Union of Operating Engineers Local 542 (“IUOE Local 542”) located in Fort Washington, Pennsylvania. IUOE Local 542 has sued Mallinckrodt individually in Pennsylvania state court. Earlier this

year, the Court of Common Pleas of Montgomery County denied Mallinckrodt's Preliminary Objections seeking to have the case dismissed. Since that time, the case has been proceeding through discovery.

314. Because of the marketing and sales efforts by Mallinckrodt's sales representatives, including Art Venio, Dr. Clauser utilized the Acthar Start Form with his patients, including the IUOE Local 542 patient treated with Acthar. As a result, UBC coordinated the payment for Acthar by IUOE Local 542 on behalf of Mallinckrodt at the inflated AWP price set by Mallinckrodt. As a result, IUOE Local 542 and its beneficiary were harmed by the scheme and conspiracy of Defendants through their direct participation in the ASAP program.

315. Dr. Clauser has treated multiple patients in Pennsylvania with Acthar. It is believed and therefore averred that such patients and their TPPS were subjected to and harmed by the scheme and conspiracy allege herein by Dr. Clauser's role as a highly paid KOL for Mallinckrodt, and his utilization of Acthar Start Forms with his patients. Dr. Clauser has treated patients with Acthar on at least the following dates for the identified conditions: June 9, 2014 (MS); September 10, 2014 (MS); September 12, 2014 (MS); October 9, 2014 (MS); October 15, 2014 (MS); February 24, 2015 (MS); April 20, 2015 (MS); June 3, 2015 (MS); and June 8, 2015 (MS).

316. Dr. Clauser prescribed Acthar for an IUOE Local 542 beneficiary, and charged the inflated AWP-based price as set by Mallinckrodt by submitting the prescription through IUOE Local 542's PBM, Express Scripts. IUOE Local 542 paid the AWP-based price charged.

317. Specifically, Dr. Clauser prescribed an unapproved 5-day dose of Acthar to treat a patient with MS, who was also a beneficiary of IUOE Local 542. Dr. Clauser filled out an

Acthar Start Form on June 29, 2011, listing “80 units/day x 5 days” for MS, and faxed the form to UBC to obtain coverage and payment from IUOE Local 542, which it did.

318. Dr. Clauser held a meeting with Mallinckrodt in his office in Allentown on Tuesday, January 8, 2013. Also in attendance were his employees, nurse practitioner Jean Bakke-Cain and registered nurse Grace Connelly.

319. The meeting was arranged by Mallinckrodt’s sales representative for the Lehigh Valley, Art Venio. Also invited to attend was one of Mallinckrodt’s top 10 KOLs in the country, Dr. Ruwani Gunawardane, a neurologist from Fulton, Maryland. While it is unknown what was said at the meeting, based on the express goals of the KOL program, it is likely that Dr. Gunawardane was brought from Maryland to Allentown to further train Dr. Clauser in the “art” of being a top Mallinckrodt KOL and spokes-doctor. It is believed and therefore averred Dr. Gunawardane also taught Dr. Clauser about the off-label uses and doses of Acthar for the treatment of his patients, including for the treatment of MS. Dr. Gunawardane specifically thanked Dr. Clauser and his staff at Lehigh Neurology about “perspectives on MS relapses and Acthar.”

320. Only discovery will reveal if Dr. Gunawardane has been paid more than a consulting fee, honoraria and travel expenses, such as whether she has been paid additional monies based on the Acthar sales generated by Dr. Clauser in the wake of her visit to him. Such a “pyramid scheme” would perhaps explain how Dr. Gunawardane has been able to generate more than \$100,000 a year working for Mallinckrodt as a KOL, in addition to maintaining a healthcare practice in Maryland.

321. According to ProPublica, Dr. Gunawardane has been paid a staggering \$1,111,326 as a paid consultant to drug companies, \$332,000 of which was paid by

Mallinckrodt. She is among the top eight largest prescribers of Acthar in the country, and is among the highest paid of Mallinckrodt’s KOLs.

322. Specifically, according to CNN, Dr. Gunawardane “received 502 payments worth \$332,393.36 -- nearly half was compensation for services, about a third was honoraria, about a sixth was for travel and lodging, and the rest was for consulting, education and food and beverage. Gunawardane filed 38 claims resulting in \$1,329,002.84 in Medicare coverage.”¹⁰ Dr. Gunawardane declined to comment when confronted by CNN. Id.

323. Dr. Clauser became a Mallinckrodt “spokes-doctor” and KOL after the January 8, 2013 meeting with Mallinckrodt and Dr. Gunawardane. Dr. Clauser has been a highly KOL for Mallinckrodt for years.

324. According to Propublica, which has only published data since the second half of 2013, Dr. Clauser was paid by Mallinckrodt at least the following disclosed sums for his promotional activity on behalf of Mallinckrodt in promoting the sale of Acthar to other doctors throughout Pennsylvania and New Jersey:

Aug. 2013 - Dec. 2013	\$9,124
Jan. 2014 - Dec. 2014	\$26,959
Jan. 2015 – Dec. 2015	\$8,727
Jan. 2016 – Nov. 2016	\$18,286

¹⁰ <https://www.cnn.com/2018/06/29/health/acthar-mallinckrodt-medicare-claims-doctor-payments/index.html>

325. In the first half of 2013 alone, since the meeting with Dr. Gunawardane, Dr. Clauser served as a Mallinckrodt KOL on at least the following occasions in the following places:

January 18, 2013	Wilkes Barre, PA
March 22, 2013	East Norriton, PA
April 16, 2013	Bridgewater, NJ
April 18, 2013	Sellersville, PA
April 29, 2013	Manhattan, NY
May 14, 2013	Brooklyn, NY
May 21, 2013	King of Prussia, PA
June 26, 2013	Brooklyn, NY
August 1, 2013	Center Valley, PA

326. On multiple occasions, Dr. Clauser was paid twice by Mallinckrodt for the same services and reimbursements, in an obvious kickback to the doctor.

327. Based on the Propublica information, Mallinckrodt paid Dr. Clauser substantial “honoraria” and “consulting” fees, totaling up to at least \$59,423, for his time and effort.

328. The specific dates, locations and payments relating to Dr. Clauser’s consulting for Mallinckrodt as a KOL lies within the exclusive control of Mallinckrodt and Dr. Clauser, who have a joint interest in concealing the details of their relationship. Only discovery will reveal these details to Plaintiff and the Class.

d. Dr. Steven Urbaniak in Langhorne, Pennsylvania And IUOE Local 542’s Inflated Payments for Acthar

329. Steven Urbaniak, DO. is a board-certified neurologist with Oxford Neurology, LLC located at 940 Town Center Drive, Suite F50, Langhorne, Pennsylvania. Dr. Urbaniak is also on staff at St. Mary Medical Center in Pennsylvania.

330. Beginning in March 2013, Dr. Urbaniak treated a patient covered by IUOE Local 542. Dr. Urbaniak prescribed Acthar for the patient, and charged the inflated AWP-based price

as set by Mallinckrodt by submitting the prescription through IUOE's PBM, Express Scripts. IUOE Local 542 paid the AWP-based price charged.

331. Because of the marketing and sales efforts by Mallinckrodt's sales representatives, including Stacyann Clancy, Dr. Urbaniak utilized the Acthar Start Form with his patients, including the IUOE Local 542 patient treated with Acthar. As a result, UBC coordinated the payment for Acthar by IUOE Local 542 at the inflated AWP prices set by Mallinckrodt. As a result, IUOE Local 542 and its beneficiaries were harmed by the scheme and conspiracy of Defendants through their direct participation in the ASAP Program.

332. Specifically, it is believed and therefore averred that Dr. Urbaniak prescribed an unapproved 5-day dose of Acthar to treat MS in a beneficiary of IUOE Local 542, with the direct involvement and assistance of Mallinckrodt and UBC in securing payment at the inflated AWP for Acthar and IUOE Local 542.

333. Dr. Urbaniak has treated multiple patients in Pennsylvania with Acthar. It is believed and therefore averred that such patients and their TPPS were subjected to and harmed by the scheme and conspiracy alleged here in by Dr. Urbaniak's role as a highly-paid KOL for Mallinckrodt, and his utilization of Acthar Start Forms with his patients. Dr. Urbaniak has treated patients with Acthar for the treatment of MS and MS relapses on at least the following occasions: July 22, 2014; October 6, 2014; October 28, 2014 and December 19, 2014.

334. Stacyann Clancy is specifically identified by Relator Strunck and Pratta as having engaged in the unlawful conduct alleged in this case. *See* Struck and Pratt Cmplt, at ¶¶ 133-134.

335. Dr. Urbaniak held a meeting in his office in Langhorne on Tuesday, January 8, 2013. Also, in attendance was another doctor by the same last name, Kathy Urbaniak, M.D. At least 8 other people from Oxford Neurology also attended.

336. The meeting was arranged by Questcor’s sales representative, Stacyann Clancy, for a discussion with Mallinckrodt leading KOL, Dr. Ruwani Gunawardane.

337. While it is unknown what was specifically discussed at the 2013 meeting, it is known that Dr. Gunawardane presented on the topic of “MS Relapses and the MCR System.” Dr. Urbaniak has been a KOL for Mallinckrodt for years.

338. According to Propublica, Dr. Urbaniak was paid by Mallinckrodt at least the following disclosed sums for his promotional activity on behalf of Mallinckrodt in selling Acthar to other doctors throughout Pennsylvania:

Aug. 2013 - Dec. 2013	\$10,241
Jan. 2014 - Dec. 2014	\$3,815
Jan. 2015 – Dec. 2015	\$2,010
Jan. 2016 – Nov. 2016	\$107

339. Since the meeting with Dr. Gunawardane, Dr. Urbaniak served as a Mallinckrodt KOL on the following occasions in the following places:

March 13, 2013	New Hope, PA
May 30, 2013	Warrington, PA
July 11, 2013	Philadelphia, PA

340. Based on the Propublica information, Mallinckrodt paid with substantial “honoraria” and “consulting” fees, totaling up to \$59,423, for his time and effort.

341. The specific dates, locations and payments relating to these Dr. Urbaniak’s consulting for Mallinckrodt as a KOL lies within the exclusive control of Mallinckrodt and Dr.

Urbaniak, who have a joint interest in concealing the details of their relationship. Only discovery will reveal these details to Plaintiff and the Class.

e. Dr. Irene Greenhouse Jamison, Pennsylvania And IUOE Local 542's Inflated Payments for Acthar

342. Irene Greenhouse, M.D. is a board-certified neurology specialist with offices located at 2370 York Road, Jamison, Pennsylvania.

343. In July 2014, July 2015 and throughout 2017, Dr. Greenhouse treated a patient covered by IUOE Local 542.

344. Dr. Greenhouse prescribed Acthar for an IUOE Local 542 beneficiary, and charged the inflated AWP-based price as set by Mallinckrodt and as charged by UBC by filling out multiple Acthar Start Forms and submitting them to UBC via facsimile in order to engaged the ASAP program established by Defendants as part of their scheme to defraud TPPs. On the forms, Dr. Greenhouse listed the disease state as “multiple sclerosis”, but claimed each time that the Acthar treatment was allegedly for an MS exacerbation, in order to try to bring the prescription within the Acthar approved label. However, as set forth below, there was insufficient evidence presented by Dr. Greenhouse to support her claim of an MS exacerbation.

345. Further, each time, Dr. Greenhouse prescribed an unapproved 5-day dose of Acthar to treat the MS. As described above by Relators Strunck and Pratta, this put the patient at unnecessary risk, in view of other available, safe and effective, and even cheaper medicines. Specifically, this particular patient was trying to become pregnant. Acthar's label specifically warns that “H.P.Acthar has been shown to have an embryocidal effect. There are no adequate and well-controlled studies in pregnant women. H.P.Acthar should be use during pregnancy only if the potential benefit justifies the potential risk to the fetus.”

346. It is believed that Dr. Greenhouse never stated to UBC, or IUOE Local 542, in her submissions through the ASAP that she had made any determination that “the potential benefit justifies the potential risk to the fetus.”

347. It is believed and therefore averred that at some point prior to 2013, Dr. Greenhouse was trained in the “art” of being a top Mallinckrodt KOL and spokes-doctor by someone at Mallinckrodt, and likely another as-yet-unknown KOL.

348. Only discovery will reveal if Dr. Gunawardane was that KOL, as she has trained two other area Pennsylvania neurologists, Dr. Clauser and Dr. Urbaniak, both of whom treated IUOE beneficiaries suffering from MS with Acthar.

349. It is known that Dr. Greenhouse has been paid thousands of dollars acting as a Mallinckrodt KOL.

350. According to Propublica, which has only published data since the second half of 2013, Dr. Greenhouse was paid by Mallinckrodt at least the following disclosed sums for her promotional activity on behalf of Mallinckrodt in promoting the sale of Acthar to other doctors:

Aug. 2013 - Dec. 2013	\$35,705
Jan. 2014 - Dec. 2014	\$48,878
Jan. 2015 – Dec. 2015	\$50,278
Jan. 2016 – Nov. 2016	\$37,250

351. The specific dates, locations and payments relating to these Dr. Greenhouse’s consulting for Mallinckrodt as a KOL lies within the exclusive control of Mallinckrodt and Dr. Greenhouse, who have a joint interest in concealing the details of their relationship. Only discovery will reveal these details to Plaintiff and the Class.

352. It is known that Dr. Greenhouse has been prescribing Acthar since at least 2012, when Mallinckrodt and UBC were rolling out their schemes to promote Acthar for unapproved uses and doses in the treatment of lupus. For instance, on October 3, 2012, while Dr. Greenhouse was working for Meadowbrook Neurology on Huntingdon Pike in Huntingdon Valley, Pennsylvania she prescribed Acthar for the treatment of lupus in a patient.

353. Critically, Dr. Greenhouse asked UBC to have Mallinckrodt send her an MSL. UBC's note states "Please have a Rheum msl follow up." In other words, Defendants utilized Mallinckrodt's MSLs in their dealings with Dr. Greenhouse.

i. The case of "Patient A"

354. In this case, there is at least one example of a patient's safety being potentially put at risk, contrary to the approved Acthar label, as a direct and proximate result of the Defendants' unlawful conduct alleged herein.

355. A beneficiary of IUOE Local 542, known as "Patient A" to protect the patient's identity and HIPAA rights,¹¹ has been treated by Dr. Irene Greenhouse of Jamison, Pennsylvania for MS. As explained below, Dr. Greenhouse is a Mallinckrodt KOL. Dr. Greenhouse has been paid tens of thousands of dollars by Mallinckrodt to act as a "spokes-doctor" for the company for years. Specifically, on information and belief, Dr. Greenhouse has been paid by Mallinckrodt to speak to other doctors about her experience in prescribing Acthar for the treatment of MS exacerbations, including treatment with an unapproved, 5-day dosing regimen, like she has prescribed for her MS patients for years.

¹¹ Defendants are fully aware of the identity of Patient A, as they alone possess and control the documents from which the above facts were gleaned. They only way Plaintiff and its counsel will be able to glean such facts about Local 420's own patient, and the patients of other TPPs in the Class, will be through discovery in this case.

356. In 2017, Dr. Greenhouse prescribed an unapproved, 5-day dosing regimen of Acthar for the treatment of a supposed MS exacerbation in Patient A. She did this on multiple occasions in 2017. Dr. Greenhouse had previously prescribed the same unapproved, 5-day dosing regimen for Acthar to Patient A for a supposed MS exacerbation in the years 2014 and 2015, while Mallinckrodt and UBC were actively promoting Acthar for such unapproved dose. Specifically, she prescribed Acthar to Patient A for a 5-day dose in July of 2014 and July of 2015.

357. Both times, IUOE Local 542 was charged the inflated, AWP-based price for Acthar by UBC and Mallinckrodt, despite the fact the Acthar was not approved for such a treatment.

358. Both times, IUOE Local 542 paid a discounted price off the AWP, pursuant to its plan with Express Scripts. These amounts were \$32,180.68 for the July 2014 prescription, and \$34,653.95 for the July 2015 prescription, respectively.

359. The inflated AWPs at the time for Acthar were \$37,951.20 and \$40,840.80, respectively.

360. Patient A paid co-pays of \$40.00 and \$20.00 for these administrations, respectively. However, Patient A was not charged a co-pay for the 2017 prescriptions. Instead, Patient A was transferred to Mallinckrodt's Patient Assistance Program ("PAP"), which PAP was run by UBC. Patient A was approved by UBC and Mallinckrodt for long-term PAP, meaning Patient A was not required to pay any co-pay for any present or future Acthar prescriptions. Thus, IUOE Local 542 was directly and proximately harmed by the Defendants' conduct in running the PAP as described below, as part of the overall Marketing Enterprise.

361. The FDA-approved label for Acthar states that Acthar may be prescribed for an MS exacerbation. It is unclear that Patient A ever suffered from an MS exacerbation. Such conclusion was questioned by the medical professionals who reviewed Dr. Greenhouse's prescription, and denied such claim.

362. As set forth above, Acthar is only approved to treat MS exacerbations.

363. It is also unclear whether Patient A was treated with approved generic methylprednisolone, or other approved treatments, prior to being prescribed Acthar, as required.

364. In the 2015 prescription, Dr. Greenhouse wrote on the Acthar Start Form that Patient A was given Solu-Medrol IV "2 yrs ago" and that it "failed" then. In other words, in 2013, Patient A was apparently prescribed Solu-Medrol IV. However, she was prescribed Acthar in both 2014 and 2015 without having been prescribed Solu-Medrol or any other approved treatment for MS. Since Acthar is not a "first-line" treatment for MS, a failure of other approved medications is required. But, that was not done by Dr. Greenhouse. Instead, she referenced only an apparent 2013 prior treatment with methylprednisolone as the basis for claiming that Acthar was indicated in later years, to wit, 2014 and 2015. No FDA-approved clinical studies have been done to support such a conclusion.

365. In view of the foregoing, the 2014 and 2015 prescriptions for Acthar were off label in several respects: (1) there was no clear evidence of an MS exacerbation, as required; (2) there was no first-line treatment with an approved medication, and a failure of the same, prior to the Acthar administration, as required; (3) the dose of Acthar prescribed was for an approved, 5-day course of therapy.

366. Beyond the fact that the Acthar prescribed to Patient A in 2014 and 2015 was unapproved, IUOE Local 542 was overcharged for such prescriptions by paying an AWP-based price, as set and charged by Defendants.

367. In 2017, Patient A was prescribed Acthar for an unapproved use and dose a third time.

368. However, this time, IUOE Local 542 had put in place an independent, second level review as part of its mandatory PA. MCMC, LLC of Quincy Massachusetts independently reviews drug claim decisions made by Express Script when challenged on appeal. This was important because, after Dr. Greenhouse prescribed the Acthar to Patient A in March 2017, it was denied.

369. Dr. Greenhouse and UBC then appealed the decision. It was denied a second time.

370. When the claim was first presented in March 2017, IUOE Local 542's PBM denied the claim for the following reasons:

Coverage is provided in situations where that the patient is unable to use high-dose intravenous (IV) corticosteroids; OR, the patient has tried high-dose corticosteroids administered IV (methylprednisolone 500 to 1,000 mg IV daily for 3 to 5 days) and experienced a severe or limiting adverse effect. Coverage cannot be authorized at this time.

371. In other words, IUOE's PBM was not presented with sufficient evidence that Patient A had been given high-dose corticosteroids, like Solu-Medrol IV, in 2017, and that such treatment failed. As a result, IUOE Local 542 coverage was denied.

372. On the second appeal, Dr. Greenhouse's Acthar prescription was denied again on April 15, 2017 by MCMC for the below stated reasons:

Acthar is approved for treating MS relapses in patients who are unable to tolerate or have an adverse reaction to steroids. In Patient A, there is no objective

evidence of a relapse as MRI's were reported [by Dr. Greenhouse] as "There were no lesions per my review". Objective evidence of MS relapse would be contrast enhancing lesions. [Patient A was] also not on any disease modifying therapy, and the symptoms could represent baseline untreated MS and not an exacerbation. The failure of prior steroids was also not clear, and the conversation with the provider [Dr. Greenhouse] was unable to clarify this. Therefore, the requested H.P. Acthar Unit/ML Vile does not meet Prior Authorization (PA) criteria.

Furthermore, the clinical literature also does not support the use as there is no clear MS exacerbation, nor is there a clear failure or adverse reaction to steroids documented. Therefore, the requested H.P. Acthar Unit/ML Vial is not medically necessary outside of PA criteria.

This determination by MCMC constitutes the final review of the services under the terms of The Plan.

373. Dr. Greenhouse prescribed the 5-day dose of Acthar to Patient A despite the fact that Patient A reported "she is trying to get pregnant". In fact, Patient A had suspended her treatment with copaxone to treat her MS because she was trying to become pregnant. The Acthar label specifically warns of potential fetal harm in patients who are pregnant.

374. The label further warns of use of Acthar in "Specific Populations" as a follows:

8.1 Pregnancy

Pregnancy Class C: H.P.Acthar has been shown to have an embryocidal effect. There are no adequate and well-controlled studies in pregnant women. H.P.Acthar should be use during pregnancy only if the potential benefit justifies the potential risk to the fetus.

375. Despite such clear warning in the Acthar label, Dr. Greenhouse prescribed an expensive, 5-day dose of Acthar for her "likely MS exacerbation and because she failed steroids in the past."

376. In fact, Patient A had only been prescribed steroids 4 years before the 2017 prescription, and there was no clear diagnosis of an MS exacerbation. This was expressly found by MCMC.

377. Yet, in arguing for coverage and payment by IUOE Local 542, on March 27, 2017, Dr. Greenhouse wrote a letter “to whom it may concern” in an effort to get IUOE Local 542 to reverse the PA denial. Dr. Greenhouse faxed the letter to UBC, which in turn forwarded it by use of the wires to as-yet-unknown other persons in an effort to get IUOE Local 542 to reverse its denial of coverage.

378. The letter states, in pertinent part, as follows:

Patient A “is experiencing severe MS exacerbation and has tried and failed IV steroids. Please approve [the] Acthar Gel which is the FDA approved medication for Multiple Sclerosis Exacerbations. ... Please help [Patient A] to get better by allowing [Patient A] to have the medication that is FDA approved.”

379. These statements were false, misleading and deceptive statements in several respects.

380. First, as MCMC found, “there is no objective evidence of a relapse”. Dr. Greenhouse’s statement that Patient A “is experiencing severe MS exacerbation” was unsupported, and “the symptoms could represent baseline untreated MS and not an exacerbation”, as MCMC also found.

381. Second, “the failure of prior steroids was also not clear, and the conversation with the provider [Dr. Greenhouse] was unable to clarify this.” Because “[Patient A was] also not on any disease modifying therapy,” as required, Dr. Greenhouse’s statement that she “has tried and failed IV steroids” was at least deceptive, if not misleading, insofar as it purported to indicate that Patient A recently tried steroids in relation to the claimed 2017 MS exacerbation.

382. Finally, the FDA has not “approved” Acthar for Patient A’s condition, as urged by Dr. Greenhouse.

383. The fact that Defendants coordinated the drafting and sending of a misleading and deceptive letter, by use of the mail and wires, in an effort to bypass IUOE Local 542’s PA in

order to get the TPP to pay for the high-priced Acthar for an unapproved use and dose is direct evidence of their scheme and conspiracy alleged in this case.

384. On May 24, 2017, Dr. Greenhouse filled out a “Prior Authorization Form” provided by Independence Blue Cross (“IBC”), the major medical healthcare provider of Patient A. By the form, Dr. Greenhouse requested coverage for the unapproved, 5-day dose of Acthar for a supposed MS exacerbation. In response to a request for “any member information that may be useful in the decision-making process, Dr. Greenhouse misleadingly reported “my pt [patient] *has tried* and [sic] IV steroids with no relief.” Emphasis added. The statement was misleading because, in plain English, “has” is the third person singular of the present tense of “have”, denoting a present use of IV steroids, not the prior use 4 years ago. As before, Dr. Greenhouse was deliberately trying to convince IBC that Patient A has failed IV steroids in 2017 in order to garner approval of the off-label prescription of Acthar.

385. The blank form was faxed to Dr. Greenhouse on May 24, 2017 at 2:41p.m. Dr. Greenhouse filled out the form and then faxed it to UBC at 3:38p.m. UBC then interceded with IBC to get it to cover the Acthar based on the misleading information provided by Dr. Greenhouse.

4. Mallinckrodt’s and UBC’s False and Misleading Marketing About the “Mechanisms of Action” for Acthar, in Promoting the Drug for a Wide Range of Unapproved Uses and Doses, Putting Patients at Substantial Risk.

386. In addition to the lack of proven safety or efficacy for the host of uses and doses that Mallinckrodt and UBC promote Acthar in neurology, nephrology and rheumatology, and the dangerousness of Acthar for such unapproved uses and doses, Mallinckrodt and UBC do not know, and have not known since it acquired the product was acquired by Mallinckrodt in 2001,

the exact “mechanism of action” (“MOA”) for Acthar. In other words, neither Mallinckrodt nor UBC know how Acthar works, even to treat the disease states for which it has been approved.

387. In view of this lack of understanding of the MOA for Acthar, the FDA has mandated the following lines be included on the Acthar label:

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The mechanism of action of H.P. Acthar Gel in the treatment of infantile spasms is unknown.

388. In 2010, in response to Mallinckrodt’s request for approval of the IS indication for Acthar, the FDA expressly found that “the exact mechanism of action for specific indications, such as the treatment of infantile spasms, is not known.” DDMAC Memo at 1 (emphasis added). The FDA made such finding in part due to the fact that the original FDA approval in 1952 was based upon limited clinical evaluation of patients, not any current FDA-approved clinical study standards.

389. Despite these unambiguous findings by the FDA, both Mallinckrodt and UBC misrepresent and deceive providers, patients and TPPs into prescribing, taking and paying for Acthar, respectively, for unapproved uses and doses. Mallinckrodt has repeatedly and consistently misrepresented to the public the “value” of Acthar for specific indications, including the rheumatoid disorder for which the Local 420 beneficiary was prescribed Acthar. UBC coordinates the Acthar prescription from inception to payment, answering all questions posed by providers, patients and TPPs, including questions about the MOA for Acthar and whether it works for the prescribed indication.

390. Internally, Mallinckrodt concedes that, even for IS, the “[e]xact mechanisms of action of ACTH in the treatment of infantile spasms are not fully understood.”

391. Publically, however, Mallinckrodt has falsely and misleadingly promoted the sale of Acthar for the long-term treatment of MS, NS, SLE and RA, despite its limited approval for only acute exacerbations of disease.

392. Indeed, it has been part of Mallinckrodt's long-term business strategy since 2007 to promote the administration of Acthar as a maintenance medication for all indications where it is approved only for the treatment of acute episodes or exacerbations of disease.

393. Prior to the launch of the new strategy in 2007, Mallinckrodt's top executives, at best, had a "rudimentary understanding" of the Acthar MOA. Nevertheless, Mallinckrodt's top executives have routinely misrepresented the value of Acthar for the treatment of specific unapproved indications, despite the FDA's express finding that the MOA is not known.

394. For instance, Mallinckrodt's former COO Steve Carrt has admitted under oath before the FTC that "in 2006, we had only a very rudimentary understanding of either Acthar or synthetic ACTH, understanding both products evolved considerably between 2006 and the present time."

395. Since that time, Mallinckrodt's knowledge of the MOA for Acthar has remained "rudimentary" as to all the disease states for which Mallinckrodt markets and sells Acthar, including and especially those for which there has been no FDA approval.

396. This lack of understanding has not impacted Mallinckrodt's training of UBC's RS's who alone interface with the providers, patients and payors, passing on Mallinckrodt's misleading and deceptive messages about Acthar's purported uses and benefits.

397. In August 2011, when asked directly by investors about the Acthar MOA, Questcor CEO Don Bailey claimed publicly that while "Acthar is an extraction of porcine pituitaries", "it's an undisclosed composition, so that's a trade secret." In other words, he misled

the public that the company would not disclose the “undisclosed composition” of Acthar, when in actuality it was unknown. Bailey further claimed falsely that it is a barrier to entry for competitors to enter the market for ACTH drugs because “there are probably multiple active ingredients” in Acthar, and “there are multiple peptides within Acthar, and they’re undisclosed.” (emphasis supplied).

398. Claiming that the MOA for Acthar is “undisclosed” blatantly misrepresents that it is somehow known by Mallinckrodt, but is not being disclosed by the company because it is supposedly a “trade secret”. It can only be a trade secret if it is known.

399. During that same investor conference call, CEO Bailey was questioned about the MOA for Acthar, and stated “there is actually a fair amount of confusion about the mechanism of action here.” He then passed the question to Christine Clemson, Mallinckrodt MSL. Clemson falsely claimed, “[w]e now know [about Acthar’s] effects in, say, MS are really relevant to its direct effect on the immune system. ...So that’s really the primary, direct effect of Acthar that I discuss in an MS’s office. This is new information....” *Id.* (emphasis supplied).

400. As discussed below, in the case of the beneficiaries of IUOE Local 542, Mallinckrodt’s and UBC’s direct misrepresentations about the purported MOA of Acthar in the treatment of MS exacerbations, through their MSLs/sales representatives and RSs, respectively, led to those beneficiaries receiving unapproved, off label, 5-day dosing of Acthar, for which IUOE Local 542 was forced to pay inflated Acthar prices.

401. Both Mallinckrodt and UBC have encouraged KOLs to speak to patients and TPPs about the MOA of Acthar in order to get them to agree to prescriptions of Acthar for unapproved uses and doses.

402. For instance, in the case of Dr. Mandel, when one of his patients was denied coverage for Acthar on February 27, 2014, he faxed UBC a letter to be sued with the “Clinical Appeals Department” of Express Scripts. In the letter, Dr. Mandel falsely and misleadingly requested coverage for RA – not an RA exacerbation. He claimed “medical necessity” and stated “H.P. Acthar Gel is FDA approved therapy for Rheumatoid Arthritis”. He then stated “Acthar has a very unique mechanism of action”, and proceeded to try to explain what the FDA has mandated on the Acthar label is “unknown.” This letter was used by UBC and Mallinckrodt to get coverage for the patient for RA, an unapproved use.

403. Since the time of the adoption of the new strategy in 2007, Mallinckrodt has been spending money in research to try to discover and understand the MOA of Acthar, all the while promoting the drug as safe and effective for the treatment of diseases for which it has not been approved and for which its efficacy remains unknown, especially at the doses Defendants promote.

404. Despite its longstanding “rudimentary understanding” of the Acthar MOA, Mallinckrodt and UBC have continued to aggressively promote Acthar as both safe and effective, and valuable, for the treatment of a host of diseases, including as long-term, maintenance medication for MS, NS, SLE and RA.

405. Due to their aggressive marketing, Mallinckrodt sales representatives and MSLs, and UBC “Reimbursement Specialists” or “RSs”, are questioned most often by doctors about the efficacy of Acthar and its MOA. Mallinckrodt sales representatives and MSLs, and UBC’s RSs, are trained to misrepresent the truth about Acthar’s MOA and its limited efficacy, and to deceive providers, patients and TPPs about the limited benefits of Acthar.

406. Because it operates Mallinckrodt's HUB for the ASAP program, these same questions are most often posed to UBC. These people are known as "Reimbursement Specialists" or "RSs", and they are assigned to each patient at the time of the Acthar Start Form submission or initial call to UBC. The RS then follows the patient's case until delivery of Acthar and payment by the TPP.

407. The UBC RS directly communicates the false and misleading messages of Mallinckrodt about Acthar, its uses and doses, including off label uses and doses, its supposed benefits in relation to other treatments, and its price and value for the price charged. They do this because they are directly trained by Mallinckrodt MSLs and other employees sent by Mallinckrodt to train all new RSs, and to update the training of existing RSs. UBC RSs are not clinical pharmacists; they have no medical degrees. They are specialists in prescription drug reimbursement. In other words, they specialize in finding ways to get high priced drugs like Acthar paid for by TPPs like Local 420.

408. Neither Mallinckrodt's nor UBC's marketing and promotion of Acthar described in this Complaint has been submitted to, reviewed by, or approved by the FDA, as required.

409. In light of that, as discussed below, the DOJ has chosen to intervene in the lawsuit brought by Qui Tam Relators Strunck, Pratta and Clark to advance the claims of these former Mallinckrodt employees challenging such marketing and sales scheme. See generally, Strunck & Pratta Complaint and U.S. Complaint filed in this Court.

5. Mallinckrodt Funds "Patient Assistance Programs" Run by UBC to Fund Patients Copays to Circumvent Patient Complaints and TPP Advance Awareness about Acthar's High Prices.

410. In the U.S. Complaint in Intervention, the government includes detailed allegations about Mallinckrodt's use and employment of free Acthar and copay assistance

through a “scheme [that] allowed the Company to continually raise Acthar’s price yet market it as ‘free’ to patients and doctors, shifting the drug’s ever-increasing cost to Medicare.” Id. at ¶ 2.

411. So too, such Marketing Scheme allowed Mallinckrodt, with UBC’s direct assistance and intervention in running the Mallinckrodt “Patient Assistance Program” or “PAP”, to shift the high costs of Acthar to private payors, like Local 420, IUOE Local 542 and the Class of TPPs and their beneficiaries.

412. As the government alleges, “Mallinckrodt [and UBC] knew that the cost of Acthar would make it difficult to sell because there were cheaper, effective competitor drugs available to treat certain of its approved uses, namely acute exacerbations of multiple sclerosis, lupus and rheumatoid arthritis. Mallinckrodt [and UBC] intended to overcome this difficulty and did so by making the drug ‘free’ to patients by subsidizing their Medicare copayments. By doing so, Mallinckrodt [and UBC] could maintain the high price of Acthar to maximize [their] own sales revenues, but minimize the risk that the drug’s high price would impede doctors and patients from using it.” Id. at ¶ 4 (brackets added).

413. “Mallinckrodt knew that paying copay subsidies to Medicare [and private] patients was illegal. To achieve the same end indirectly, Mallinckrodt paid copay subsidies through a foundation that Mallinckrodt used as a conduit to do so. At the foundation, call the Chronic Disease Fund (now d/b/a Good Days)(collectively “CDF”), Mallinckrodt designed the supposed ‘patient assistance’ funds that paid copays for Acthar only and then funded them through ‘donations’ knowing that its money would be used on Acthar copays to the exclusion of other drugs. Mallinckrodt then sent Medicare [and private payor] patients to CDF in order to receive virtually guaranteed, Mallinckrodt-funded subsidies. The Company also obtained and used data about the number of patients at CDF, the subsidies paid to them, and the amount of

money Mallinckrodt needed to pay to keep covering Acthar copays. Mallinckrodt financed the funds accordingly.” *Id.* at ¶ 5 (brackets added).

414. “Mallinckrodt sent patients to CDF via the Company’s ‘reimbursement hub’ [UBC] for Acthar, called the Acthar Support and Access Program (“ASAP”). Mallinckrodt controlled ASAP, which included a call-center that received referrals for Acthar from physician offices and patients. Mallinckrodt’s sales force took steps to ensure that any Acthar prescriptions were routed through ASAP so the Company could track them. After a referral came in to ASAP, as discussed in more detail [herein], ASAP [via UBC] provided patients with an ‘automatic offering’ of copay assistance via CDF.” *Id.* at ¶ 100 (brackets added).

415. Mallinckrodt set up a specific fund with CDF titled the “MS Acute Exacerbation Fund” for which Acthar was the only listed treatment, in order to ensure that all monies “donated” by Mallinckrodt were earmarked exclusively for patients receiving Acthar. Then, all the provider, working with UBC, need to do was to list the patient’s indication as an “MS Exacerbation” in order to send the patient to CDF for copay assistance with their Acthar copay. The MS Acute Exacerbation Fund had at least twice the available benefit per patient than any other program offered by CDF – at least \$8,000. That was likely to ensure that any copay up to 20% would be covered.

416. As the government alleges, “Mallinckrodt, via ASAP [and the UBC HUB], referred Acthar patients to the fund regardless of whether they were using the drug for an acute exacerbation or on a long-term basis. Internally, Mallinckrodt referred to this longer-term use of Acthar in MS patients as ‘pulse maintenance’ or ‘pulse’ therapy.” *Id.* at ¶102 (brackets added).

417. In this case, Local 420 paid the high cost of Acthar for a beneficiary with RA, while IUOE Local 542 paid the high cost of Acthar for several beneficiaries with MS. With

respect to the alleged PAP conduct, Patient A was provided long term PAP assistance for a supposed MS exacerbation, through a program run by the Chronic Disease Fund (“CDF”) and funded exclusively by money provided by Mallinckrodt. UBC directed Patient A to the CDF for such PAP.

418. Plaintiff alleges that Mallinckrodt employed UBC, the HUB, to coordinate sending the patients to CDF, like Patient A. As described above, once IOUE Local 542’s PA successfully denied the appeal of the coverage decision for a supposed MS exacerbation, Dr. Greenhouse, UBC and Mallinckrodt sought to circumvent that PA by referring Patient A to “Long Term PAP”, as opposed to “Short Term PAP”.

419. Long Term PAP is defined as “PAP support for prequalified patients that are either uninsured” – not Patient A – “or rendered underinsured such that coverage is otherwise unattainable” – not Patient A. In contrast, Short Term PAP is defined as “PAP support for Patients experiencing ... Multiple Sclerosis Acute Exacerbation”, supposedly Patient A according to the diagnosis of Dr. Greenhouse in 2014, 2015 and 2017.

420. If Patient A suffered from MS exacerbation, she could not have been eligible for Long Term PAP. Nevertheless, in accordance with the object of the Marketing and Pricing Schemes alleged, Patient A was referred by Defendants and Dr. Greenhouse to Long Term PAP.

421. Similar to the MS Acute Exacerbation Fund, Defendants set up additional PAP funds with CDF. One such additional fund was the “RA Exacerbation Fund”. Again, the amount of the benefit was more than twice that of other funds at CDF, at least \$8,000 per patient, and the only drug treatment available under the fund was Acthar. Thus, Defendants replicated the success they had with the MS fund in other disease areas, including RA.

THE QUI TAM WHISTLEBLOWER COMPLAINT AGAINST MALLINCKRODT

422. On April 30, 2019, CNN reported that the United States Department of Justice (“DOJ”) had intervened in a false claims act action brought by two former employees of Mallinckrodt.

423. The intervention actually took place the month before, on March 6, 2019, but the case was sealed at the time. See Plaintiff Under Seal v. Defendant Under Seal, Civil Action No. 12-CV-0175-BMS, E.D.Pa., at Dkt. No. 55. The government’s decision to intervene, a relatively rare occurrence, was done after the government conducted its own extensive investigation of the claims by the former employees and concluded that the allegations are credible.

424. The case, now known as U.S. ex. Rel. Charles Strunck and Lisa Pratta, was filed in 2012 by Charles Strunck, New York-based former Multiple Sclerosis (“MS”) Sales Specialist for Questcor, and Lisa Pratta, a New Jersey-based Acthar neurology specialist for both Questcor and Mallinckrodt (collectively, the “Relators”). Strunck worked from September 2010 through August 2011, while Pratta worked from September 2010 through June 2017.

425. As reported by CNN, and as averred in their Qui Tam Complaint, the Relators allege that Mallinckrodt has engaged in a long-standing scheme to bribe doctors to prescribe Acthar at the exorbitant, inflated prices detailed herein. They claim there was a “culture” at Mallinckrodt designed to sell Acthar at all costs, from lying to the FDA to offering bribes to doctors.

426. Importantly, Mallinckrodt has not denied the allegations. Instead, Mallinckrodt claims the conduct alleged is a “legacy matter” involving Questcor and its conduct prior to Mallinckrodt’s acquisition.

427. However, Relator Pratta, who worked at both Questcor and Mallinckrodt after the 2014 acquisition, has alleged that the conduct continues at Mallinckrodt.

428. In a conference call with investors held May 7, 2019, CEO Mark Trudeau publicly stated that the company has reserved for the settlement of the Relators' case and is actively pursuing settlement which he stated is "likely to resolve sooner than later".

429. The conduct alleged by Relators involved kickbacks to doctors in the form of free Acthar, as well as active concealment by Mallinckrodt of the conduct for years.

430. For this reason, Local 420 did not know and could not have known about such unlawful conduct until the earliest date of April 30, 2019. As a result, Plaintiff's claims stated herein premised upon the unlawful conduct revealed by the Relators' case are timely.

431. Plaintiff had no way of knowing that Mallinckrodt was paying doctors thousands of dollars to prescribe Acthar to their patients.

432. The kickback scheme involved the promotion of Acthar to treat disease states for which Acthar was not the "gold standard", as in the case of IS, and for treatments that were not covered by the Acthar label.

433. For instance, Acthar is approved to treat acute exacerbations of disease. But the scheme uncovered by Relators involved widespread promotion of Acthar for the long-term treatment of disease as a maintenance medication.

434. Further, the scheme uncovered that Mallinckrodt sales representatives and MSLs were trained to promote unapproved doses of Acthar. For instance, in the treatment of MS exacerbations, Acthar is not approved by the FDA for 5-day dosing.

435. In the case of Local 420's beneficiary, the patient has been prescribed Acthar for years to treat a rheumatic disorder, not an RA exacerbation. As a result of Mallinckrodt's

promotional effort, instead of treating Local 420's beneficiary for an acute exacerbation, or flare-up, the patient has been given four prescriptions over the course of two months, forcing Local 420 to pay over one-hundred and fifty thousand dollars for Acthar.

436. In the case of IUOE Local 542, several beneficiaries have been treated by KOLs cultivated by Mallinckrodt to promote unapproved 5-day dosing for MS exacerbations. These prescriptions have cost IUOE Local 542 hundreds of thousands of dollars in expenditures for unapproved treatments which, in the case of Patient A, potentially put the patient at risk for a problem pregnancy.

437. The conduct revealed by the Relators goes to the manner in which Mallinckrodt was able to convince doctors to prescribe the high-priced Acthar, after the Defendant' conspired and agreed to raise the prices and maintain the prices at artificial levels, and to promote the sale of Acthar to such high prices through highly paid KOLs. The conduct involved systematically promoting and marketing Acthar for unapproved, off-label uses and doses, including the rheumatic disorder for which the Local 420 beneficiary has been prescribed Acthar.

438. The scheme involved compensating sales representatives thousands of dollars to promote the sale of Acthar for unapproved uses and doses, to benefit Mallinckrodt and the sales reps. Sales representatives have been paid tens of thousands of dollars for such promotional efforts. As detailed in the Relators' Qui Tam Complaint, one sales representative was paid a \$124,000 bonus in the second quarter of 2011, including \$75,000 for just one month. Others received bonuses of \$110,000 and \$80,000 in the same period.

439. The compensation of sales reps was directly tied to sales growth, a growth that was possible by expanding the approved uses for Acthar which had a narrow, limited market of patients.

440. Mallinckrodt employed a team of MSLs, like Sagar Shah, who were directed by Nikki Mutschler to join with sales specialists, like Strunck and Pratta to promote the sale of Acthar for unapproved uses. The Relators have identified the sales representatives who detailed the doctors of patients covered by IUOE Local 542, like Stacyann Clancy.

441. To hide the fact that the promotional effort was for unapproved, off-label uses, Mallinckrodt referred to such uses as “new indications.”

442. The sales of Acthar for these “new indications” became a primary focus for Mallinckrodt, as it strived to grow its revenue to the more than \$1 billion in sales it achieves each year for Acthar alone.

443. Mallinckrodt achieved such exponential growth, despite the price increases detailed herein, by providing valuable remunerations to doctors to induce and encourage them to prescribe Acthar for unapproved uses and doses.

444. As the Relators’ Qui Tam Complaint reveals, and as Local 420 alleges herein, Mallinckrodt engaged in such conduct in violation of the consumer fraud laws by providing secret kickbacks to doctors throughout the country, including Pennsylvania, to get them to prescribe Acthar at exorbitant prices, which Local 420 has been forced to pay. That is why Plaintiff seeks declaratory and injunctive relief against Mallinckrodt to end such practices.

CLASS ACTION ALLEGATIONS

445. Local 420 brings this action pursuant to Rules 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure, on behalf of itself and other similarly-situated persons and entities, and their beneficiaries, in Pennsylvania and throughout the country. The proposed Class includes:

All third-party payors and their beneficiaries in the United States and its Territories that paid for Acthar from August 2007 through

the present for any unapproved indication or dose.

446. Excluded from the above Class are: (a) Mallinckrodt and any entity in which Mallinckrodt has a controlling interest, and its legal representatives, offices, directors, assignees and successors, (b) any co-conspirators with Mallinckrodt, and (c) any government payor, including Medicare, Medicaid and/or Tricare.

Numerosity

447. The proposed Class consists of thousands of private payors in the proposed Class located throughout Pennsylvania and the United States, based on the fact that Mallinckrodt has sold thousands of vials of Acthar in each quarter over the last few years alone. Thus, the Class is so numerous that joinder of all of its members is impractical.

448. Despite the size of the Class, its members are easily identifiable and ascertainable, as each patient has been required by Mallinckrodt since 2007 to fill out an Acthar Start Form as part of the ASAP. As a result, the records needed to identify the members of the Class, and the payments made by TPPs and their beneficiaries in the Class, are in the hands of the Mallinckrodt and/or its agents.

Typicality

449. Local 420's claims are typical of the claims of the Class, in that the representative Plaintiff is an entity who, like other Class Members, paid for Acthar at the inflated prices due to the unlawful conduct of Mallinckrodt. Local 420, like all similarly-situated Class members, has been damaged and has sustained economic injuries in the form of overcharges by the misconduct of Mallinckrodt, because it paid higher prices than it would have paid absent Mallinckrodt's improper actions.

Adequacy of Representation

450. Local 420 can and will fairly and adequately represent and protect the interests of the Class. Plaintiff has no interest that conflicts with or is antagonistic to the interests of the Class.

451. Local 420 is represented by counsel who are experienced and competent in the prosecution of complex actions, including consumer fraud class actions.

Commonality

452. The factual and legal bases for Mallinckrodt's misconduct are common to Class members and represent a common thread of consumer fraud resulting in injury to Plaintiff and the Class. Common questions of law and fact in this case include, but are not limited to, the following:

- a. whether Mallinckrodt engaged in the unlawful marketing and sales scheme alleged;
- b. whether Mallinckrodt engaged physicians as "spoke-doctors" in the scheme involving KOLs alleged;
- c. whether Mallinckrodt artificially inflated the prices of Acthar;
- d. whether Plaintiff and the Class have been overcharged and thus damaged by paying artificially inflated prices for Acthar as a result of Mallinckrodt's unlawful conduct;
- e. whether Mallinckrodt engaged in the conduct involving PAPs and the payment of patients copays;
- f. whether Mallinckrodt engaged in conduct in violation of RICO;
- g. whether Mallinckrodt engaged in conduct in violation of the consumer fraud laws of Pennsylvania and other states;
- h. whether Mallinckrodt has been unjustly enriched by its unlawful conduct;
- i. whether Mallinckrodt negligently misrepresented Acthar to Plaintiff and the Class;

- j. whether Mallinckrodt engaged in a conspiracy and/or aided and abetted others in deceiving Plaintiff and the Class about Acthar and Acthar pricing, and concealing the truth about its unlawful conduct;
- k. whether Mallinckrodt is liable to Plaintiff and the Class for statutory damages for conduct actionable under the consumer fraud laws of Pennsylvania and other states;
- l. whether Plaintiff and members of the Class are entitled to declaratory and injunctive relief as to Mallinckrodt's conduct;
- m. whether Plaintiff and members of the Class are entitled to compensatory damages, and, if so, the nature of such damages;
- n. whether Plaintiff and members of the Class are entitled to statutory damages, including treble damages;
- o. the proper measure of damages; and
- p. whether Plaintiff and members of the Class are entitled to an award of punitive damages, reasonable attorneys' fees, prejudgment interest, post-judgment interest, costs of suit, and other appropriate relief under the circumstances of this case.

Predominance

453. These common questions of law and fact predominate over questions, if any, that may affect only individual members because Mallinckrodt has acted and refused to act on grounds generally applicable to the entire Class. Such generally applicable conduct is inherent in Mallinckrodt's unfair and deceptive conduct alleged herein.

Superiority

454. A class action is superior to any other available method for the fair and efficient adjudication of this controversy in that, among other things, such treatment will permit a large number of similarly-situated persons and entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of effort and expense that numerous individual actions would engender.

455. The prosecution of separate actions by individual members of the Plaintiff Class would create a risk of inconsistent or varying adjudications with respect to individual members of the Class. These adjudications would establish incompatible standards of conduct for Mallinckrodt which would, as a practical matter, be disparities of the claims of the other members not parties to the adjudications or substantially impair or impede their ability to protect their interests.

456. Mallinckrodt has acted or refused to act on grounds generally applicable to all members of the Class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the Class as a whole.

457. Accordingly, class certification is appropriate under Rule 23(b)(1)(A), 23(b)(1)(B), 23(b)(2) and 23(b)(3).

FORMATION OF THE UNLAWFUL ACTHAR MARKETING ENTERPRISE

458. Beginning in 2007 and continuing to the present, each Defendant implemented a marketing and promotion campaign by combining its own respective significant personnel and financial resources with peer-influencing physicians (known as KOLs) through which Defendants (i) falsely and deceptively oversold the safety and efficacy of Acthar, (ii) failed to adequately warn of, and affirmatively misled the medical community regarding the risks, benefits and value of Acthar and (iii) unlawfully promoted Acthar for usage in populations for which it had not received FDA approval and for which the safety and efficacy had not been established through adequate clinical evidence. This association-in-fact created by Defendants is denominated in this Complaint as the Acthar Marketing Enterprise. Defendants and their associated participants established the Acthar Marketing Enterprise to accomplish the common goal of causing increased prescribing activity of Mallinckrodt's Acthar for off-label uses and

doses for which Acthar was not proven to be safe, effective or useful. The scheme was accomplished through fraudulent, or false and deceptive, claims of efficacy and safety, medical usefulness, and for unlawful, off-label purposes.

459. First, to execute their Acthar Marketing Enterprise successfully, each Defendant had to create a parallel marketing structure that appeared independent from the ordinary promotion forces – they each did so both to avoid federal regulations concerning off-label promotion and to create the façade of independence behind the misleading message of safety, efficacy and non-indicated usage they each wished to promote. Defendants targeted primarily speaking events, seminars, continuing medical education (“CME”) events as well as other physician gatherings. Defendants worked with and paid leading KOLS to create content for such speaking events that misrepresented the safety, efficacy, and usefulness of Acthar for off-label uses, and paid these KOLs to deliver the disguised promotional messages to unsuspecting physician attendees.

460. The goal of the Acthar Marketing Enterprise was intentionally complementary and mutually reinforcing. The Defendants’ Acthar Marketing Enterprise was succeeded in distorting and polluting the medical discourse and medical literature surrounding Acthar to such a degree that physicians and patients were rendered incapable of making objective and informed decisions concerning the appropriateness of Acthar for off-label and label-expanding usage.

A. FORMATION OF THE ILLEGAL ACTHAR MARKETING ENTERPRISE

461. Defendants’ Acthar Marketing Enterprise centered on hosting numerous events where KOL doctors rained and/or approved by Defendants would falsely oversell the efficacy and safety of Acthar and would provide favorable information on the off-label use of Acthar, often under conditions where physicians would be compensated for attending the presentation.

Mallinckrodt funded and continues to fund scores of such events between approximately 2007 to present.

462. The Acthar Marketing Enterprise employed improper and unlawful sales and marketing practices, including: (a) deliberately misrepresenting the safety and medical efficacy of Acthar for a variety of off-label uses; including 5-day dosing for MS exacerbations; (b) knowingly misrepresenting the existence and findings of scientific data, studies, reports and clinical trials concerning the safety and medical efficacy of Acthar for both approved indications and for a variety of off-label uses and doses; (c) deliberately concealing negative findings or the absence of positive findings relating to the off-label uses of Acthar; (d) wrongfully and illegally compensating physicians for causing the prescribing of Acthar; (e) knowingly publishing articles, studies and reports misrepresenting the scientific credibility of data and touting the medical efficacy of Acthar for both on-label and off-label uses, and then disseminating copies of such studies by the thousands to the medical community as part of their marketing; (f) intentionally misrepresenting and concealing Defendants' role and participation in the creation and sponsorship of a variety of events, articles and publications used to sell Acthar to off-label markets; and (g) intentionally misrepresenting and concealing the financial ties between Defendants and other participants in the Acthar Marketing Enterprise.

463. Defendants' scheme reaped significant financial gain. From 2007 to present, Defendants revenues from the sale of Acthar soared into the millions and billions of dollars. Eventually, as a result of each Defendants' Acthar Marketing Enterprise efforts and unbeknownst to the Plaintiff and Class Member TPPS, the vast majority of Acthar prescriptions were for off-label uses. Sales of each drug have grown at a significant rate each year. Currently, Acthar represents over \$1 billion in revenue to Mallinckrodt.

464. All of the participants in Defendants Acthar Marketing Enterprise associated with the respective Defendants with the common purpose of aiding them in marketing Acthar for off-label uses and to achieve “market expansion” of these uses. Each of the participants received substantial revenue or other consideration from each Defendant for their efforts in the scheme to promote Acthar off-label. The more successful these marketing events were, the more events there would be in the future and the more fees and revenues each of the participants would receive for participating in the events. For these reasons, all of the participants knowingly and willingly agreed to assist each of the Defendants in their off-label promotion of Acthar, notwithstanding the fact that such a promotional campaign required the systematic repetition of false and misleading statements to, and the commercial bribery (through kickbacks) of hundreds of physicians throughout Pennsylvania and the United States, and that the promotion of Acthar for off-label indications by Defendants was illegal.

465. Each Defendant exercised control over and participated in the Acthar Marketing Enterprise. Each Defendant compensated the other participants for their efforts, and controlled the money flow to the participating physicians. Defendants each closely monitored all activities and events to ensure the expected representations and marketing messages related to the off-label uses of Acthar were made to physicians attending the events. Following each event, each Defendant tracked attending physicians’ prescribing habits to ensure that the messaging was successful in causing prescribing activity for Acthar.

1. Role of Physicians in the Acthar Marketing Enterprise.

466. One of the principal strategies pursued by all Defendants in their Acthar marketing Enterprise was to target key physicians to serve as “thought leaders”, or KOLs. These doctors promoted Acthar to their peers through peer selling programs by (i) touting Acthar’s

supposed off-label uses; (ii) claiming that Acthar was being widely used by other physicians for off-label uses; and (iii) claiming that they were privy to the latest clinical data that had not been released yet, but which would support off-label use.

467. To lure physicians to participate in the Acthar Marketing Enterprise, Mallinckrodt sales representatives and MSLs approached target doctors and informed them of an interest in funding research opportunities and clinical trials at their practices and institutions. Doctors who were willing to speak favorable about Acthar could receive substantial funds in the form of research grants or other monies. In addition, these doctors were frequently remunerated for other less-defined services, including “consulting” and “advisory board” services. Mallinckrodt instructed its sales department to select doctors at the major teaching hospitals to become Acthar “experts” and KOLs who would in turn deliver the Acthar message to other physicians to grow sales. This was done formally to other physicians at marketing events or informally to colleagues within a hospital or medical practice, or at a dinner or lunch roundtable.

468. Having recruited these physicians, Defendants’ Acthar Marketing Enterprise created an explosion in the off-label use of Acthar by artificially creating the perception that physician specialists were clinically using Acthar and investigating with positive results their efficacy in off-label uses on their own initiative, and not as a result of the illegal marketing activities and inducements. Mallinckrodt developed a stable of physicians to create this perception. Mallinckrodt paid these physicians to induce them to write PA denial appeals, letters to the editor and other documents that favorably discussed the off-label use of Acthar. Mallinckrodt also paid these physicians (in addition to providing free travel to resorts, free lodging and free meals) to induce them to give talks at medical education seminars, advisory boards, consultants’ meetings, speakers bureaus and similar events where the primary focus of

the discussion was the off-label use of Acthar. The physicians who accepted these benefits and agreed to promote Acthar off-label to other doctors were physician participants in the Defendants’ Acthar Marketing Enterprise. The individual physician participants received tens of thousands of dollars, and in some cases hundreds of thousands, to promote the off-label uses of Acthar. Participation in the Enterprise through sham “authorships” and serving as presenting “faculty” at CME events and other honoraria also enhanced the physician participants’ professional reputations.

469. The return on investment (“ROI”) in Defendants’ Marketing Enterprise was highly favorable.

470. Physician participants were absolutely critical to the success of Defendants’ Acthar Marketing Enterprise. Indeed, the marketing plans drafted by Mallinckrodt required their participation. The participation of physicians allowed Mallinckrodt to disguise promotional events as educational events or consultants’ meetings. Moreover, as noted above, Mallinckrodt and UBC knew that peer-to-peer selling was far more persuasive than traditional drug rep detailing.¹² Primary care physicians are more likely to follow the advice of a Professor of Medicine at Johns Hopkins or another teaching hospital than that of a sales rep. By funneling the payments to physician participants through the vendor participants, the Acthar Marketing Enterprise could hide the speakers’ financial ties with Defendants, and the Enterprise was able to mislead the physician-listeners into believing that the speakers were not biased and that the events were not promotional. As a result, the vast amounts of money the participating physicians

¹² When a sales representative “details” a physician, often during a call to the physicians’ office during work hours, the representative delivers to the physician the pharmaceutical company’s key selling messages for one or more pharmaceutical products. In some cases, the sales pitch is accompanied by handing out free samples of the product and/or approved materials delivered to the physician, such as sales aids, slides or branded merchandise such as pens and prescription pads. Here, Defendants were able to steer physicians through ASAP to UBC for PAP.

received from the Defendants, for speaking and other purposes, was largely hidden from the physicians who attended events at which the participating physicians spoke.

471. Physicians who participated in the Acthar Marketing Enterprise either as speakers or as authors, entered into mutually advantageous contractual relationships with Mallinckrodt. The more favorable a physician's statements were, the more he or she could expect to receive in the form of speaker fees, consulting fees, advisory board fees, and research grants. Physicians who refused to deliver the favorable off-label message that Mallinckrodt wanted were blackballed and would not receive additional payments.

472. The participating physicians knew that minimal scientific evidence supported the use of Acthar for the off-label uses and that the type of clinical evidence that existed was insufficient, under the accepted standards in the medical profession, to represent that Acthar worked for the unapproved indications.

473. All of the physician participants had personal relationships with employees of Defendants, whether the Mallinckrodt sales reps and MSLs, or the UBC RSs, and frequently Mallinckrodt recommended specific individual participants for event.

474. Plaintiff does not at this time know the identity of all of the physician participants, which likely number in the hundreds.

475. The Defendants' Acthar Marketing Enterprise sponsored hundreds of events across the country between 2007 and the present. Through Propublica, the Plaintiff is only able to identify physicians by payments, including travel, food, lodging and entertainment benefits they received for events held at resorts or out of town hotels.

476. In order to implement their respective plans to transform Acthar into the blockbuster drug it has become, despite a small on-label patient population, Acthar created a

separate Acthar Marketing Enterprise composed of each Defendant, and dozens of physician participants, some of whom are listed above and others whose identities will be revealed in discovery. These participants all acted together and under each Defendants' control in promoting Acthar's off-label to the healthcare industry, employing numerous tactics with an enormous degree of success.

477. Mallinckrodt hosted numerous seminars and events over the course of several years that were falsely represented to be neutral, educational forums. At these events, the roster of physician participants provided misleading and deceptive information to fellow physicians on the off-label uses of Acthar (i.e. peer-to-peer marketing). The physician participants were not independent, but received behind-the-scenes coaching and remuneration from Mallinckrodt and/or its vendors, and often used slide decks and PowerPoint presentations prepared by the marketing teams of Mallinckrodt Targeted audience members, many of whom were primary care physicians or specialists in MS, NS and RA, were not aware that the specialists (including prominent neurologist and nephrologists) speaking to them were in fact delivering, and being paid to deliver, the off-label marketing message of Mallinckrodt.

478. In addition, the sales force of Mallinckrodt promoted Acthar to physicians through "details" or sales calls to physicians' offices. On these sales calls, sales representatives often using a sales aid and/or sales script developed by Mallinckrodt "detail" the physician on the off-label uses of Acthar. In addition, the sales representatives were instructed to deliver to physicians reprints of medical journal articles advocating the off-label use of Acthar, many of which were created by the KOLs paid by Mallinckrodt, and to notify physicians of and ask for their attendance at upcoming CME events and lectures sponsored by Mallinckrodt pursuant to

the Acthar Marketing Enterprise. All aspects of each Defendants' Acthar Marketing Enterprise were mutually reinforcing.

479. All components of each Defendants' Acthar Marketing Enterprise were fully integrated and operated under each Defendants' exclusive control, through the ASAP program.

DEFENDANTS' USE OF THE MAILS AND WIRES TO CREATE AND MANAGE THEIR FRAUDULENT SCHEME

480. Defendants used, and knowingly caused the use of, mail and interstate wire communications to create, execute, and manage their fraudulent schemes, as well as to further them. This scheme involved the national marketing and sale plan that comprised ASAP, and encompassed physicians and consumers across the country.

481. Defendants' use of, and causing the use of, the mails and wires in furtherance of their schemes to defraud involved thousands of communications and transmission through the Class period all over the country, including:

- Transmission through mail and wire marketing and advertising materials about the off-label uses of Acthar to and from physicians across the country, including and especially the Acthar Start Forms which were faxed to UBC;
- Communications and transmissions, including financial payments, from Defendants or vendors to participants in the Acthar Marketing Enterprise, including physicians, discussing and relating to the production and publication of articles and dissemination of materials misrepresenting the off-label uses and safety and efficacy of Acthar.
- Communications with Plaintiff and the Class Members and their beneficiaries, other health insurers, and patients, including payments for Acthar to be made based on misrepresentations concerning their safety, efficacy, effectiveness, and usefulness; and
- Communications, payments and monetary transfers using the wires concerning the receipt and distribution of the proceeds of Defendants' improper scheme.

482. In addition, Defendants' respective corporate headquarters have communicated, and knowingly cause communications, by United States mail, telephone and facsimile with or by

various local district managers, MSLs, RSs and pharmaceutical sales representatives, in furtherance of Defendants' scheme.

COUNT I
VIOLATION OF 18 U.S.C. § 1962(C)

483. Plaintiff hereby incorporates by reference the averments of the foregoing paragraphs as if fully set forth herein and further alleges as follows:

484. Defendants are each "persons" within the meaning of 18 U.S.C. § 1961(3), who each conducted the affairs of the Acthar Marketing Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c). Plaintiff and the members of the Class are also persons.

485. The Acthar Marketing Enterprise is an association in fact enterprise affecting interstate commerce within the meaning of 18 U.S.C. § 1961(4) consisting of (i) Mallinckrodt, and its MSLs and sales representatives, (ii) UBC, and its RSs, and (iii) KOLs, both named and unnamed in this Complaint. At all relevant times, in violation of 18 U.S.C. § 1962(c), Mallinckrodt, UBC, the KOLs and other co-conspirators conducted the affairs of an association-in-fact enterprise within the meaning of 18 U.S.C. § 1961(4), including their directors, employees, and agents who assisted in carrying out their alleged scheme.

486. The Acthar Marketing Enterprise falls within the meaning of 18 U.S.C. § 1961(4) and consists of a group of "persons" associated together for the common purpose of promoting Acthar for off-label uses and doses and earning profits therefrom.

487. Mallinckrodt and UBC have conducted and participated in the affairs of the Acthar Marketing Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and 1961(5), which includes multiple instances of mail fraud in violation of 18 U.S.C. § 1341, and multiple instances of wire fraud in violation of 18 U.S.C. § 1343, as

described above. The unlawful predicate acts of racketeering activity committed, or caused to be committed, by Mallinckrodt and UBC throughout the Class Period number in the thousands, and Mallinckrodt and UBC committed, or caused to be committed, at least two of the predicate acts within the requisite ten (10) year period, a period which began in 2007 and continues through the present.

488. This enterprise was manifested by and through the ASAP program, but was made up of the three components of the alleged scheme: the Distribution Scheme, the Pricing Scheme and the Marketing Scheme. Accordingly, the enterprise concerned the marketing and sale of Acthar pursuant to the 2007 new strategy with each of these components described herein.

489. The Acthar Marketing Enterprise was begun in 2007, and is an ongoing and continuing business organization consisting of both corporations (*i.e.*, Mallinckrodt and UBC) and individuals (*s* MSLs, RSs, KOLs), associated for the common purpose of distributing, pricing and marketing Acthar to Plaintiff and the Class at exorbitant AWP prices, and deriving substantial profits from these activities.

490. The Acthar Marketing Enterprise engages in and affects interstate commerce because it engages in the following activities across state boundaries: the distribution, pricing, marketing, sale, and/or purchase of Acthar, the transmission of WAC and AWP pricing information to the pricing compendia, ASAP program literature (including the Acthar Start Form at Exhibit “A” hereto), the operating of the ASAP program website, communications with providers, patients and TPPs by UBC as part of ASAP, and the transmission and/or the receipt of invoices and payments related to the prescription and use of Acthar. Through these activities the Acthar Enterprise markets, distributes and sells Acthar to thousands of individual patients, including those receiving prescription drug benefits from the Plaintiff and the Class.

491. The Acthar Marketing Enterprise has functioned as a continuing unit, as evidenced by the continuing coordination of activities between Mallinckrodt and UBC. There is a common communication network by which Mallinckrodt and UBC (and their agents and employees, including MSLs, RSs and KOLs) shared and continue to share information on a regular basis for all times relevant to this lawsuit, but beginning at least in 2007 and continuing through the present. Typically, this communication occurred by use of the wires and mails, in which Mallinckrodt, UBC and KOLs all agree to charge TPPs inflated AWP prices for Acthar to the patients of TPPs, like Local 420, and other Class members. These entities functioned as a continuing unit for the purposes of implementing the scheme to inflate the prices of Acthar by and through ASAP. When issues arose during the scheme, each agreed to take actions to hide the scheme and to continue its existence.

492. Defendants have exerted control over the Acthar Enterprise, have associations with the Enterprise, and have directly or indirectly conducted or participated in the conduct of the affairs of the ASAP Enterprise in the following ways:

- a. Defendants have directly controlled the AWP price at which Plaintiff and the Class purchase Acthar;
- b. Defendants have directly controlled the AWP price at which Plaintiff and the Class reimburse for Acthar;
- c. Defendants have directly controlled the ASAP program materials and website which enroll patients in an exclusive distribution network for the administration of Acthar, allowing Mallinckrodt and UBC to conduct their unconscionable and unfair pricing of Acthar;
- d. Defendants have directly controlled the exclusive distribution network for Acthar through the ASAP Enterprise;
- e. Defendants have relied on their employees to promote the ASAP program through the marketing alleged herein, through the mail and the wires;

- f. Defendants placed their own employees and agents in positions of authority and control over the Acthar Marketing Enterprise;
- g. Defendants controlled the content of the messages being delivered by the Acthar Marketing Enterprise at each seminar, event, and presentation, in the publications being used and presented, in the direct communications with providers, patients and payors, all of which included misinformation and false and misleading statements about the safety, efficacy, effectiveness, usefulness, and value of Acthar for off-label uses;
- h. Defendants have participated in the affairs of the ASAP Enterprise by using a fraudulent scheme to market and sell Acthar at inflated prices;
- i. Mallinckrodt has selected and approved physicians to serve as KOLs, who in turn work with UBC under the ASAP to deliver off-label prescriptions of Acthar for payment by TPPs; and
- j. Defendants worked to ensure that the Acthar prescribed by KOLs and other providers were paid for by TPPs at the inflated AWP's charged by them.

493. Defendants have conducted and participated in the affairs of the ASAP Enterprise through a pattern of racketeering activity that includes acts indictable under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1345, relating to wire fraud. Defendants' pattern of racketeering activity likely involved hundreds, if not thousands, of separate instances of the use of the United States mail, private shipping services, facsimiles, or interstate wires, including the internet, in furtherance of its fraudulent and unlawful scheme. Each of these fraudulent mailing and interstate wire transmissions separately constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Collectively, these violations constitute a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5) in which the Defendants intended to defraud Plaintiff and members of the Class.

494. As described in greater detail herein, Defendants' fraudulent scheme consisted of confining patients to an exclusive distribution network, such that they could drastically inflate the prices charged for Acthar. By conducting this program through the mail and wires,

Defendants engaged in a repeated, fraudulent, and unlawful course of conduct constituting a pattern of racketeering.

495. As detailed above, the Acthar Marketing Enterprise consisted of: (a) deliberately misrepresenting, and causing others to misrepresent, the uses for which Acthar was safe and effective so the Plaintiff and the Class Members paid for this drug at inflated prices to treat conditions and/or symptoms for which it was not scientifically proven to be safe, effective, useful and valuable; (b) presenting seminars, events, in-person meetings and telephonic communications misrepresenting the off-label uses of Acthar for which Defendants knew Acthar was not proven to be scientifically safe, effective, useful or valuable to physicians and other healthcare providers; (c) disseminating materials created pursuant to the Acthar Marketing Enterprise and using those materials to misrepresent, and cause others to misrepresent, the uses for which Acthar was safe, effective, useful and valuable; and (d) actively concealing, and causing others to conceal, information about the safety, efficacy, usefulness and value of Acthar to treat conditions for which it had not been approved by the FDA.

496. These racketeering activities amounted to a continuing course of conduct, with similar pattern and purpose, intended to harm Plaintiff and the Class to pay excessive amounts for Acthar. Each instance of racketeering activity perpetuated by the Defendants was related, and had a similar intended purpose, involved similar participants and methods of execution, and have the same results affecting the same class of victims, including Plaintiff and the Class. Defendants had engaged in this pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the Acthar Marketing Enterprise.

497. Defendants' pattern of racketeering activities alleged herein are separate and distinct from each other.

498. Defendants' pattern of racketeering activities had directly and proximately caused Plaintiff and members of the Class to be injured in their property insofar as Plaintiff and members of the Class have overpaid thousands of dollars in inflated reimbursements and other payments for Acthar. Plaintiff's and the Class Members' injuries were directly caused by the predicate acts and are not attributable to any independent or intervening forces; their injuries were a foreseeable and natural consequence of the Defendants' scheme; there is no difficulty posed by having to apportion damages among Class Members with potentially different standing or levels of injury because there are no other injured parties besides Plaintiff and the TPP Class Members in this case, who are the parties directly injured by the Defendants' RICO violations. No one other than Plaintiff and the Class could vindicate the rights and claims of Plaintiff and the Class.

499. By virtue of these violations of 18 U.S.C. § 1962(c), Defendants are jointly and severally liable to Plaintiff and the Class for three times the damages Plaintiff and the Class have sustained, plus the costs of this suit, including reasonable attorney's fees.

COUNT II
CONSPIRING TO VIOLATE 18 U.S.C. § 1962(c)
(18 U.S.C. § 1962(d))

500. Plaintiff hereby incorporates by reference the preceding and following paragraphs hereof as if fully set forth herein and further allege as follows.

501. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b), or (c) of this section." 18 USC § 1962(d).

502. Defendants violated section 1962(d) by conspiring to associate with a racketeering enterprise, in violation of 18 U.S.C. § 1962(c). Mallinckrodt knowingly joined

UBC and others in a conspiracy to inflate the prices of Acthar and marketing the off-label uses and doses of Acthar in violation of § 1962(c).

503. The object of this conspiracy is to and has been to conduct or participate in, directly or indirectly, the conduct of the affairs of the Acthar Marketing Enterprise described herein, through a pattern of racketeering activity that directly cause injury to the business or property of Plaintiff and the Class within the meaning of 18 U.S.C. § 1964(c). The corporate defendants conspired with, inter alia, the sales representatives, MSLs, RSs, KOLs and others to promote Acthar and suppress information about the harms know to result from Acthar use.

504. Defendants and their co-conspirators have engaged in numerous overt and predicate fraudulent racketeering activities in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Plaintiff and the Class of money.

505. That Mallinckrodt knew and adopted the criminal purpose of the Enterprise is evident from its own documents and public statements of its officers. Mallinckrodt communications reflect an express illegal agreement between Mallinckrodt and UBC to form and operate the ASAP in furtherance of the Acthar Marketing Enterprise. Mallinckrodt's officers stated that it was this agreement in 2007 that was the hallmark of a new strategy to increase revenues and profits.

506. The nature of the above-described AbbVie Defendants' co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracies gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent acts have been and are part of an overall pattern of racketeering activity. In other words, the

Defendants adopted the goal of furthering or facilitating the conspiracy, and were aware of the essential nature and scope of the Acthar Marketing Enterprise and intended to participate in it.

507. Additionally, Defendants' conduct in sending e-mails, faxes and other communications to each other to direct the distribution and sale of Acthar through ASAP is consistent with the existence of an agreement to carry out the scheme to inflate prices and maximize profits.

508. Defendants actively furthered the goals of the Acthar Marketing Enterprise to defraud end payors, like Plaintiff. They changed the distribution scheme for Acthar with the intention that the changes would allow the Pricing Scheme to be effectuated; engaged in frequent discussions with between each other about the plan to raise Acthar prices and to promote the sale of Acthar at these new high prices for unapproved uses and doses in the marketplace; and communicated with KOLs and other providers about the same.

509. The Defendants sought to and have engaged in the commission of and continue to commit overt acts, including the following unlawful racketeering predicate acts: a) multiple instances of mail and wire fraud violations of 18 U.S.C. §§ 1341 and 1342; b) multiple instances of mail fraud violation of 18 U.S.C §§ 1341 and 1346; c) multiple instances of wire fraud violations of 18 U.S.C. §§ 1341 and 1346; and d) multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

510. The Defendants' violations of the above federal laws and the effects thereof detailed above are continuing and will continue.

511. Plaintiff and members of the Class have been injured in their property by reason of these violations in that Plaintiff and members of the Class have paid millions of dollars in

overpayments for Acthar that they would not have paid had the Defendants not conspired to violate 18 U.S.C. § 1962(c).

512. Injuries suffered by Plaintiff and members of the Class were directly and proximately caused by the Defendants' racketeering activity as described above. As also set forth above, these injuries would not have occurred but for the Defendants' RICO predicate act violations, and they involved concrete financial losses to the Plaintiff and the Class Members.

513. Patients, physicians, and TPPs, including Plaintiff and the Class, directly relied on the racketeering activities of the Defendants' and the Acthar Marketing Enterprise. Plaintiff and the Class Members, both directly and indirectly, relied on the representations as to the necessity, approval and safety of Acthar as promoted by the Defendants. Because the Defendants controlled all knowledge upon which the claims of Acthar's necessity, approval and safety were based, all Class Members, as well as other members of the medical and consuming public were obligated to rely on the Defendants' representations about Acthar. Further, the Defendants perpetuated this reliance by taking the steps itemized above to suppress the dissemination of any critical information about Acthar.

514. As co-conspirators, Mallinckrodt and UBC are jointly and severally liable for all damage that occurred as a result of both their actions in furtherance of the conspiracy to raise prices of Acthar and market the sale of Acthar at inflated prices for unapproved uses and doses. Mallinckrodt is liable for all damages arising from UBC's conduct in furtherance of the scheme, as it UBC liable for all damages from Mallinckrodt's conduct in furtherance of the scheme.

515. By virtue of these violations of 18 U.S.C. § 1962(d), the Defendants are liable to Plaintiff and the Class Members for three times the damages Plaintiff and the Class Members have sustained, plus the cost of this suit, including reasonable attorneys' fees.

516. By reason of the foregoing, and as a direct and proximate result of the Defendants' fraudulent misrepresentations, Plaintiff and the Class Members have suffered damages. Plaintiff and the Class Members are entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

517. By reason of the foregoing, Plaintiff and the Class Members have been damaged as against the Defendants in a sum that exceeds the jurisdiction of all lower courts.

COUNT III
PENNSYLVANIA UNFAIR TRADE PRACTICES AND
CONSUMER PROTECTION LAW

518. Plaintiff hereby incorporates by reference the preceding and following averments as if fully set forth herein and further alleges as follows.

519. Pennsylvania's Unfair Trade Practices and Consumer Protection Law, 73 Pa. Stat. Ann. §§201, et seq. ("UTPCPL") makes unlawful any "unfair methods of competition" and "unfair or deceptive acts or practices", including the following, among others:

(ii) Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of goods or services;

(v) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation or connection that he does not have;

(vii) Representing that goods or services are of a particular standard, quality or grade, or that goods are of a particular style or model, if they are of another;

(viii) Disparaging the goods, services or business of another by false or misleading representations of fact;

(xi) Making false or misleading statements of fact concerning the reasons for, existence of, or amounts of price reductions; and

(xxi) Engaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding.

520. The unfair methods of competition, and unfair or deceptive acts or practices, in the conduct of any trade or commerce as defined above are declared unlawful under the UTPCPL.

521. Defendants engaged in the following unfair and deceptive acts or practices, which violate the aforesaid provisions of the UTPCPL:

- a. By entering into the exclusive distribution arrangement described herein in 2007, and not disclosing the same to Local 420, Mallinckrodt and UBC engaged in deceptive acts and made misrepresentations to Plaintiff and its beneficiary that impeded Plaintiff's efforts to contain costs for specialty drugs like Acthar. By then sending (or causing to be sent) bills for Acthar which charged the artificially inflated prices, and by communicating directly with patients about the misleading messages described above, Mallinckrodt injured Plaintiff and the Class. This caused at least a likelihood of confusion or of misunderstanding as to the source, sponsorship, approval and/or certification of Acthar sold by Mallinckrodt, misrepresented the same, and/or constituted fraudulent or deceptive conduct which created a likelihood of confusion or a misunderstanding by Plaintiff.
- b. Defendants conspired and agreed to adopt the above-described ASAP program and the Acthar Start Form in 2007, and to maintain and use the ASAP and Acthar Start Form through 2018 (when Plaintiff paid for Acthar), in order to mislead and deceive Local 420 and its beneficiary about the Mallinckrodt "hub" of patient care at UBC as it concerns the new conditions for which Acthar is not indicated, and to bypass Plaintiff's efforts to contain and reduce costs for specialty drugs, especially for new indications.
- c. Starting in July 2007, Mallinckrodt issued a misleading and deceptive announcement about its new distribution strategy, but the announcement failed to disclose that all aspects of Acthar distribution, pricing and product sales were now being coordinated through UBC as part of a "hub" of services for which Mallinckrodt contracted.
- d. Mallinckrodt and UBC misled and deceived Local 420 in the decision to raise the prices of Acthar, and the lack of value of Acthar for the prices being charged, in order to intentionally and

deceptively charge false, misleading and excessive prices for Acthar, during the period between 2007 (when Mallinckrodt adopted its “new strategy” they entered into their exclusive distribution and hub arrangement), through 2018 (when Local 420 began to pay for Acthar). Mallinckrodt then falsely claimed to offer discounts off the inflated prices of Acthar, thereby misleading Plaintiff as to the reasons for, existence of, or amounts of the Acthar price reductions, in violation of sub-section (xi).

- e. Defendants acts or practices, including the failures to act and to speak the truth in the face of false, misleading and deceptive statements about Acthar’s pricing, distribution and value, constitute “other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding, in violation of sub-section (xxi).

522. The UTPCPL authorizes any person, including natural persons, corporations, trusts, partnerships, incorporated and unincorporated associations, and any other legal entities to seek an injunction, damages, costs, and reasonable attorneys’ fees to prevent and ameliorate the anticompetitive conducted described herein.

523. Local 420 is a person pursuant to the UTPCPL. Local 420 has been injured as a result of the Defendants’ conduct in violation of Pennsylvania law, by virtue of having paid for Acthar in Pennsylvania, and hereby seeks damages. Plaintiff has purchased or reimbursed the costs of multiple administrations of Acthar distributed by Defendants to Local 420 ’s beneficiary for her personal, family or household use and purpose. Because Local 420’s beneficiary paid only a minimal co-pay (\$70), Local 420 paid the bulk of the inflated prices of Acthar to Mallinckrodt.

524. The acts and practices described herein demonstrate that Mallinckrodt acted unlawfully within the meaning of the UTPCPL such that Local 420 may be awarded up to three times its actual damages sustained, and such additional relief as deemed necessary or proper. These damages consist of, inter alia, the difference between the true price of Acthar, before

Mallinckrodt began in 2007 to artificially inflate the “average wholesale price” of Acthar, and the inflated prices of Acthar charged to Plaintiff in 2018. The damages of the Class may be calculated in the same manner.

525. Local 420 seeks relief against Mallinckrodt for its unfair and deceptive conduct which allowed it to raise and fix the prices of Acthar at supra-competitive levels.

526. Local 420 was injured as a direct result of Mallinckrodt’s conduct in violation of the UTPCPL sections above, and hereby seeks damages.

WHEREFORE, Steamfitters Local Union No. 420 demands that judgment be entered in its favor and against Defendants in an amount to be determined at trial, including but not limited to costs, attorneys’ fees, and such other relief deemed just and appropriate by this Court.

COUNT IV
DEFENDANTS’ VIOLATIONS OF OTHER STATE
CONSUMER PROTECTION LAWS

527. Plaintiff hereby incorporates by reference the preceding and following averments as if fully set forth herein and further alleges as follows:

528. Mallinckrodt violated the consumer protection laws of all other states by engaging in unfair methods of competition and unfair deceptive acts and practices as described herein. Plaintiff brings claims under the laws of these states on behalf of the consumer purchasers of Acthar in such states. Excluded from this case are the states of Iowa which do not allow consumers to sue. Plaintiff does not seek class certification of consumer fraud claims under the laws of Alabama, Georgia, Mississippi, and South Carolina, as those state laws do not permit class actions. However, the individual claims of consumers in those states should be permitted to be advanced in this lawsuit to benefit from those this Court’s rulings on Mallinckrodt’s conduct, especially as to the declaratory and injunctive relief sought by the Plaintiff.

**Alabama’s Deceptive Trade Practices Act (“Alabama DTPA”)
Ala. Code §§ 8-19-1, *et seq.***

529. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Alabama’s Deceptive Trade Practices Act, Ala. Code § 8-19-1, *et seq.*

530. Alabama Code § 8-19-5(27) declares that “[e]ngaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce” is unlawful.

531. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the Alabama DTPA.

532. The DTPA authorizes any person, including “a natural person, corporation, ... ” to seek an injunction, damages, costs, and reasonable attorneys’ fees to prevent and remedy the unfair and deceptive conduct described herein.

533. Mallinckrodt marketed and sold Acthar in Alabama pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein.

534. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Alabama are persons under the DTPA. Each has been injured as a direct and proximate result of Mallinckrodt’s unconscionable, unfair, and deceptive conduct in violation of the DTPA, and each hereby seeks damages, through their representative Local 420.

**Alaska’s Unfair Trade Practices and Consumer Protection Act (“UTPCPA”) Alaska
Stat. §§ 45.50.471, *et seq.***

535. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska’s Unfair Trade Practices and Consumer Protection Act, Alaska Stat. § 45.50.471, *et seq.*

536. Alaska Statute 45.50.471(a) declares that “[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of trade or commerce” are unlawful. Alaska Statute 45.50.471(b)(12) provides that the terms “unfair methods of competition” and “unfair or deceptive acts or practices” include using or employing deception, fraud, false pretense, false promise, misrepresentation, or knowingly concealing, suppressing, or omitting a material fact with intent that others rely upon the concealment, suppression or omission in connection with the sale or advertisement of goods or services, whether or not a person has in fact been misled, deceived or damaged.

537. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the Alaska UTPCPA.

538. The UTPCPA authorizes any person, including “a natural person, corporation, ...” to seek an injunction, damages, costs, and reasonable attorneys’ fees to prevent and remedy the unfair and deceptive conduct described herein.

539. Mallinckrodt marketed and sold Acthar in Alaska pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein.

540. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Alaska are persons under the UTPCPA. Each has been injured as a direct and proximate result of Mallinckrodt’s unconscionable, unfair, and deceptive conduct in violation of the UTPCPA, and each hereby seeks damages, through their representative Local 420.

**Arizona Consumer Fraud Act (“Arizona CFA”)
Ariz. Rev. Stat. § 44-1522, *et seq.***

541. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of the Arizona CFA, Ariz. Rev. Stat. § 44-1522, *et seq.*

542. The Arizona CFA is a broadly drafted remedial provision designed to eliminate unlawful practices in merchant-consumer transactions.

543. By the Arizona CFA, an unlawful practice is defined as follows: “[t]he act, use, or employment by any person of any deception, deceptive act or practice, fraud, false pretense, false promise, misrepresentation, or concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise whether or not any person has in fact been misled, deceived, or damaged thereby . . .” § 44-1522(A).

544. The term “deceptive” has been interpreted to include representations that have a “tendency and capacity” to convey misleading impressions to consumers even though interpretations that would not be misleading also are possible.

545. Technical correctness of the representations is irrelevant if the capacity to mislead is found. Additionally, a deceptive representation or practice may be found where earlier misrepresentations are corrected before the consumer agrees to a contract.

546. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the Arizona CFA.

547. The CFA authorizes any person, including “a natural person, corporation, ...” to seek an injunction, damages, costs, and reasonable attorneys’ fees to prevent and remedy the unfair and deceptive conduct described herein.

548. Mallinckrodt marketed and sold Acthar in Arizona pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein.

549. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Arizona are persons under the CFA. Each has been injured as a direct

and proximate result of Mallinckrodt's unconscionable, unfair, and deceptive conduct in violation of the CFA, and each hereby seeks damages, through their representative Local 420.

Arkansas Deceptive Trade Practices Act ("ADTPA")
Ark. Code § 4-88-101, *et seq.*

550. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*

551. Among other things, Ark. Code Ann. § 4-88-107 prohibits "[k]nowingly making a false representation as to the characteristics, ingredients, uses, benefits, alterations, source, sponsorship, approval, or certification of goods or services. . . ." and prohibits "[a]dvertising the goods or services with the intent not to sell them as advertised. . . ." Ark. Code Ann. § 4-88-107 (a)(1) & (3).

552. Under Ark. Code Ann. § 4-88-113 (f), a private cause of action is afforded to any person who suffers actual damage or injury.

553. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the ADTPA.

554. The ADTPA authorizes any person, including "a natural person, corporation, . . ." to seek an injunction, damages, costs, and reasonable attorneys' fees to prevent and remedy the unfair and deceptive conduct described herein.

555. Mallinckrodt marketed and sold Acthar in Arkansas pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein.

556. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Arkansas are persons under the ADTPA. Each has been injured as a direct and proximate result of Mallinckrodt's unconscionable, unfair, and deceptive conduct in violation of the ADTPA, and each hereby seeks damages, through their representative Local 420.

**California Business and Professions Code (“Section 17200”),
Cal. Bus. & Prof. Code § 17200, et seq**

557. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code § 17200, et seq.

558. Section 17200 is violated if a business practice is unlawful or unfair or deceptive. “[A] practice is prohibited as ‘unfair’ or ‘deceptive’ even if not ‘unlawful’ and vice versa.”

559. To show that a business practice is deceptive, the plaintiff must show that members of the public are likely to be deceived.

560. The deceptive business practices prong of Section 17200 does not require establishing that anyone was actually deceived, relied on the fraudulent practice or sustained any damage.

561. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under Section 17200.

562. Section 17200 authorizes any person, including “a natural person, corporation, ...” to seek an injunction, damages, costs, and reasonable attorneys’ fees to prevent and remedy the unfair and deceptive conduct described herein.

563. Questcor was originally based in California and marketed and sold Acthar throughout California pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein. Mallinckrodt, now based in New Jersey, has continued such conduct.

564. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in California are persons under Section 17200. Each has been injured as a direct and proximate result of Mallinckrodt’s unconscionable, unfair, and deceptive conduct in violation of Section 17200, and each hereby seeks damages, through their representative Local 420.

**Colorado Consumer Protection Act (CCPA),
Colo. Rev. Stat. § 6-1-105, et seq.**

565. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices or has made false representations in violation of Colo. Rev. Stat. § 6-1-105, et seq.

566. To establish a claim under the Colorado Consumer Protection Act (CCPA), a private citizen must prove five elements: (1) the defendant engaged in an unfair or deceptive trade practice; (2) the deceptive trade practice occurred in the course of the defendant's business; (3) the deceptive trade practice significantly impacted the public as actual or potential customers of the defendant's business; (4) the plaintiff suffered an injury to a legally protected interest; and (5) the deceptive trade practice caused the plaintiff's injury.

567. The unconscionable, unfair and deceptive acts and practices described herein are thus unlawful under CCPA. Mallinckrodt engaged in the unfair and deceptive trade practices described herein, which deceptive trade practices occurred in the course of the defendant's business. The deceptive trade practice significantly impacted the public as actual or potential customers of the defendant's business. Members of the Class who purchased Acthar in Colorado suffered an injury to a legally protected interest by their payment of money for a drug that was unapproved, unsafe, ineffective and cost more than other equally or more effective medicines. The deceptive trade practice thus caused the plaintiff's injury.

568. Mallinckrodt marketed and sold Acthar in Colorado pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein.

569. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Colorado are persons under the CCPA. Each has been injured as a direct and proximate result of Mallinckrodt's unconscionable, unfair, and deceptive conduct in violation of the CCPA, and each hereby seeks damages, through their representative Local 420.

**Connecticut Unfair Trade Practices Act (“CUTPA”),
Conn. Gen. Stat. § 42-110b, et seq.**

570. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, et seq.

571. The CUPTA expressly admonishes that “[n]o person shall engage in unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce.” Conn. Gen. Stat. § 42-110b(a). The same section also provides that “[i]t is the intent of the legislature that in construing subsection (a) if this section [that] the courts of this state shall be guided by interpretations given by the [FTC] and the federal courts to Section 5(a)(1) of the Federal Trade Commission Act.

572. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the CUTPA.

573. The CUTPA authorizes any person, including “a natural person, corporation, limited liability company, trust, partnership, incorporated or unincorporated association, and any other legal entity” to seek an injunction, damages, costs, and reasonable attorneys’ fees to prevent and remedy the unfair and deceptive conduct described herein.

574. Members of the Class who purchased Acthar at inflated prices are persons pursuant to the CUTPA and each has been injured as a result of the Defendants’ unconscionable, unfair, and deceptive conduct in violation of the CUTPA, and hereby seeks damages. One such person is Sheet Metals Workers Local 40 of Hartford Connecticut (“SMW Local 40”), represented by the same undersigned Plaintiff counsel. SMW Local 40 has sued separately in Connecticut state court.

575. The facts and circumstances described herein demonstrate that Mallinckrodt acted unlawfully within the meaning of the CUTPA such that members of the Class may be awarded

actual damages sustained as well as punitive damages, and such additional, equitable relief as deemed necessary or proper.

576. Plaintiff and the Class seek relief against Mallinckrodt for its unconscionable, unfair, and deceptive commercial practices with regard to their scheme to sell Acthar to patients through KOLs at inflated prices by an unfair and deceptive scheme involving kickbacks and other inducements.

577. Mallinckrodt created restrictions on trade and commerce in Connecticut through the creation of the exclusive arrangement for the distribution and sale Acthar.

578. Mallinckrodt then agreed to raise the prices of Acthar to inflated levels, and charged such prices in Connecticut to TPPs like SMW Local 40. As described herein, Mallinckrodt charged the supracompetitive prices of Acthar through the ASAP Program.

579. This unconscionable, unfair, and deceptive conduct caused members of the Class in Connecticut, like SMW Local 40, to pay prices for Acthar significantly greater than in an otherwise competitive market. Therefore, SMW Local 40 and members of the Class in Connecticut are entitled to relief under the CUTPA.

580. Plaintiff and the Class were injured as a direct and proximate result of the Mallinckrodt's conduct in violation of Connecticut law and hereby seek declaratory and injunctive relief and damages.

**Consumer Fraud Act ("Delaware CFA"),
Del. Code Ann. tit. 6, § 2513**

581. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, et seq.

582. The unconscionable, unfair and deceptive acts and practices described herein are thus unlawful under Delaware CFA.

583. Mallinckrodt marketed and sold Acthar in Delaware pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein.

584. Specifically, the beneficiary of Local 420 resides in Delaware. Although she treated with a rheumatologist in Pennsylvania, she was obligated to pay a copay for Acthar.

585. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Delaware are persons under the CFA. Each has been injured as a direct and proximate result of Mallinckrodt's unconscionable, unfair, and deceptive conduct in violation of the CFA, and each hereby seeks damages, through their representative Local 420 and its Delaware-based beneficiary.

District of Columbia Consumer Protection Procedures ("DCCPP")
D.C. Code § 28-3904, *et seq.*

586. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of D.C. Code § 28-3904, *et seq.*

587. D.C. Code § 28-3904 states "[i]t shall be a violation of this chapter for any person to engage in an unfair or deceptive trade practice, whether or not any consumer is in fact misled, deceived, or damaged thereby."

588. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the DCCPP.

589. The DCCPP authorizes any person, including "a natural person, corporation, ..." to seek an injunction, damages, costs, and reasonable attorneys' fees to prevent and remedy the unfair and deceptive conduct described herein.

590. Mallinckrodt marketed and sold Acthar in Arkansas pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein.

591. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in the District of Columbia are persons under the DCCPP. Each has been injured as a direct and proximate result of Mallinckrodt's unconscionable, unfair, and deceptive conduct in violation of the DCCPP, and each hereby seeks damages, through their representative Local 420.

Florida Deceptive & Unfair Trade Practices Act ("FDUTPA")
Florida Stat. §§ 501.201, et seq.

592. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, et seq.

593. The primary policy of the FDUTPA is "[t]o protect the consuming public and legitimate business enterprises from those who engage in unfair methods of competition, or unconscionable, deceptive, or unfair acts or practices in the conduct of any trade or commerce." Florida Stat. §§ 501.202(2).

594. A claim for damages under the FDUTPA has three elements: (1) a prohibited practice; (2) causation; and (3) actual damages.

595. Under Florida law, indirect purchasers of prescription drugs, like Plaintiff and the Class, have standing to maintain an action under the FDUTPA based on the facts alleged in this Complaint. Undersigned counsel for Plaintiff represents purchasers of Acthar located within Florida, who have decided to bring suit on their own behalf in Florida state court under FDUTPA.

596. Mallinckrodt's conduct constitutes an unfair method of competition and unfair and deceptive acts or practices because Mallinckrodt's conduct caused Florida-based members of the Class to pay artificially inflated prices for Acthar.

597. Mallinckrodt sold Acthar in Florida through the ASAP Program, based out of Orlando Florida, through Express Scripts subsidiary companies located in Florida, including United BioSource and Curascript. Such sales in Florida this took place under the circumstances and conditions described in this Complaint, and Mallinckrodt's conduct had a direct and substantial impact on trade and commerce in Florida. Accordingly, such conduct falls within the prohibitions in Florida Stat. §§ 501.202(2).

598. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the FDUPTA.

599. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Florida have standing to sue under the FDUPTA. Each has been injured as a direct and proximate result of Mallinckrodt's unconscionable, unfair, and deceptive conduct in violation of the FDUPTA, and each hereby seeks damages, through their representative Local 420.

Georgia Fair Business Practices Act ("FBPA")
Ga. Code Ann. §§ 10-1-390, *et seq.*

600. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Code § 10-1-393, *et seq.*

601. Ga. Code § 10-1-393(a) "[u]nfair or deceptive acts or practices in the conduct of consumer transactions and consumer acts or practices in trade or commerce are declared unlawful."

602. Mallinckrodt's conduct constitutes unfair or deceptive acts or practices in the trade or commerce of Georgia. Specifically, as described in part above, Tennessee-based Dr. Tumlin travelled to Georgia on multiple occasions as a Mallinckrodt paid KOL to promote

Mallinckrodt's misleading and deceptive message about Acthar's MOA and FDA approval, especially for NS. In fact, Dr. Tumlin travelled to suburban Atlanta for one such session.

603. As a result, doctors in Georgia became Mallinckrodt KOLs. One such doctor, Dr. Wilson, is described by former Mallinckrodt employee Barry Franks as having been part of the Mallinckrodt scheme to promote Acthar. Dr. Wilson treated a beneficiary of one of the Georgia-based clients of undersigned Plaintiff counsel. To date, such client has incurred over \$2 million in payments for Acthar, and continues to do so. The patient being treated with Acthar by Dr. Wilson is being treated for what is believed to be an off-label indication of NS. Specifically, the patient has been prescribed Acthar as a maintenance medication for the treatment of NS for multiple years. For his work on behalf of Mallinckrodt, Dr. Wilson has been paid thousands of dollars. Mallinckrodt has paid for Dr. Wilson to travel to multiple vacation locations as its "consultant" and has paid all the costs of such trips, as well as thousands of dollars of "consultant" fees and "honoraria".

604. Mallinckrodt's conduct caused Georgia-based members of the Class to pay artificially inflated prices for Acthar.

605. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the Georgia FBPA.

606. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Georgia have standing to sue under the FBPA. Each has been injured as a direct and proximate result of Mallinckrodt's unconscionable, unfair, and deceptive conduct in violation of the FBPA, and each hereby seeks damages, through their representative Local 420.

**Hawaii Unfair and Deceptive Trade Practice Act ("UDAP"),
Haw. Rev. Stat. § 480, et seq.**

607. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, et seq.

608. Haw. Rev. Stat. § 480-2(a) states that “[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are unlawful”.

609. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the Hawaii UDAP.

610. Mallinckrodt marketed and sold Acthar in Hawaii pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein

611. Only consumers, the attorney general, or the director of the office of consumer protection may bring a UDAP claim. HRS § 480-2(d). Consumers include those who “(1) purchased, attempted to purchase, or been solicited to purchase goods or services from the defendant, or (2) committed money, property, or services in a personal investment.”

612. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at the inflated prices set by Mallinckrodt and charged in Hawaii are persons under the Hawaii UDAP. Each has been injured as a direct and proximate result of Mallinckrodt’s unconscionable, unfair, and deceptive conduct in violation of the Hawaii UDAP, and each hereby seeks damages, through their representative Local 420.

613. The Hawaii UDAP also provides that “[a]ny consumer who is injured by any unfair or deceptive act or practice forbidden or declared unlawful by section 480-2: (1) May sue for damages sustained by the consumer, and, if the judgment is for the plaintiff, the plaintiff shall be awarded a sum not less than \$ 1,000 or threefold damages by the plaintiff sustained, whichever sum is the greater, and reasonable attorneys fees together with the costs of suit; and

(2) May bring proceedings to enjoin the unlawful practices, and if the decree is for the plaintiff, the plaintiff shall be awarded reasonable attorneys fees together with the cost of suit.”

614. Thus, it is not necessary that any Hawaii consumer suffered actual injury from their receipt and/or purchase of Acthar. As the Hawaii Supreme Court has held, “the plain language of the statute reflects that the legislature intended not only to protect persons who actually purchased goods or services as a result of unfair or deceptive acts and practices, but also those who attempted or were solicited to do so. ... The \$1,000.00 assured minimum recovery manifests a legislative intent to do more than simply prevent unjust enrichment at the expense of consumers who purchased relatively inexpensive goods.” *Zanakis-Pico v. Cutter Dodge, Inc.*, 98 Haw. 309, 316, 317 (2002).

**Idaho Consumer Protection Act (ICPA),
Idaho Code § 48-601, *et seq***

615. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq*.

616. Idaho Code § 48-603 provides that “[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared to be unlawful...”

617. The ICPA was enacted to protect consumers from "deceptive acts and practices in the conduct of trade or commerce." I.C. § 48-601. "[T]he ICPA defines what constitutes an unfair method of competition." *State ex rel. Wasden v. Daicel Chem. Indus., Ltd.*, 141 Idaho 102, 107, 106 P.3d 428, 433 (2005).

618. Under I.C. §48-603, “deceptive acts or practices in the conduct of any trade or commerce are unlawful where a person knows, or in the exercise of due care should know, that he has in the past, or is:

- (2) Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services;
- (3) Causing likelihood of confusion or of misunderstanding as to affiliation, connection, or association with, or certification by, another;
- (5) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have ...;
- (11) Making false or misleading statements of fact concerning the reasons for, existence of, or amounts of price reductions;
- (17) Engaging in any act or practice which is otherwise misleading, false, or deceptive to the consumer;
- (18) Engaging in any unconscionable method, act or practice in the conduct of trade or commerce, as provided in section 48-603C, Idaho Code ...

I.C. § 48-603 (2)-(3), (5), (11), (17)-(18)(statute excerpted for relevant portions only).

619. Section 48-603C defines “unconscionable methods, acts or practices” as follows:

- i. Any unconscionable method, act or practice in the conduct of any trade or commerce violates the provisions of this chapter whether it occurs before, during, or after the conduct of the trade or commerce.
- ii. In determining whether a method, act or practice is unconscionable, the following circumstances shall be taken into consideration by the court:
 - (a) Whether the alleged violator knowingly or with reason to know, took advantage of a consumer reasonably unable to protect his interest because of physical infirmity, ignorance, illiteracy, inability to understand the language of the agreement or similar factor;
 - (b) Whether, at the time the consumer transaction was entered into, the alleged violator knew or had reason to know that the price grossly exceeded the price at which similar goods or services were readily available in similar transactions by similar persons, although price alone is insufficient to prove an unconscionable method, act or practice;
 - (c) Whether the alleged violator knowingly or with reason to know, induced the consumer to enter into a transaction that was excessively one-sided in favor of the alleged violator;
 - (d) Whether the sales conduct or pattern of sales conduct would outrage or offend the public conscience, as determined by the court.

620. Beyond these legislative definitions of unfair competition, I.C. § 48-604 instructs that “[i]t is the intent of the legislature that in construing [the ICPA] due consideration and great weight shall be given to the interpretation of the federal trade commission and the federal courts

relating to section 5(a)(1) of the federal trade commission act (15 U.S.C. 45(a)(1)), as from time to time amended.”

621. Section 5(a)(1) of the FTCA provides that “[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.” 15 U.S.C. § 45(a)(1). “Federal case law as it has developed under this provision of the [FTCA], although not binding is persuasive in application of the [ICPA].” *State ex rel. Kidwell v. Master Distribs., Inc.*, 101 Idaho 447, 453, 615 P.2d 116, 122 (1980).

622. The acts and omissions of Mallinckrodt set forth herein violate the ICPA in multiple respects.

623. First, like the similar subsections of the Pennsylvania UTPCPL, Mallinckrodt’s actions violate the above-cited enumerated subsections of I.C. § 48-603 (2)-(3), (5), (11), (17)-(18).

624. Second, like the similar provisions of New Jersey law below, Mallinckrodt’s actions constitute unconscionable business practices because (1) Mallinckrodt “knowingly or with reason to know, took advantage of a consumer reasonably unable to protect his interest because of physical infirmity due to the diseases for which they were prescribed Acthar; (2) “at the time the consumer transaction was entered into, [Mallinckrodt] knew or had reason to know that the price [for Acthar] grossly exceeded the price at which similar goods or services were readily available in similar transactions by similar persons,” given the substantially cheaper costs of prednisone and other steroids; (3) Mallinckrodt “knowingly or with reason to know, induced the consumer to enter into a transaction that was excessively one-sided in favor of the alleged violator”, in light of the role of the Mallinckrodt HUB, the MSLs, the KOLs, the PAPs and other aspects of Mallinckrodt’s scheme to ensure sales of Acthar at high prices; and (4) the fact that

“the sales conduct or pattern of sales conduct would outrage or offend the public conscience”, as determined by the court based on, among other things, the Acthar price change from \$40.00 to over \$40,000 for a drug with limited uses and benefits.

625. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Idaho are consumers under the ICPA. Each has been injured as a direct and proximate result of Mallinckrodt’s unconscionable, unfair, and deceptive conduct in violation of the ICPA, and each hereby seeks damages, through their representative Local 420.

**Illinois Consumer Fraud and Deceptive Business Practices Act,
815 ILCS § 505/1, et seq**

626. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS § 505/1, et seq.

627. 815 ILCS § 505/2 states that “[u]nfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact, or the use or employment of any practice described in Section 2 of the "Uniform Deceptive Trade Practices Act", approved August 5, 1965, in the conduct of any trade or commerce are hereby declared unlawful whether any person has in fact been misled, deceived or damaged thereby. In construing this section consideration shall be given to the interpretations of the Federal Trade Commission and the federal courts relating to Section 5 (a) of the Federal Trade Commission Act.”

628. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the Illinois Act.

629. The Illinois Act authorizes any person, including “a natural person, corporation, ...” to seek an injunction, damages, costs, and reasonable attorneys’ fees to prevent and remedy the unfair and deceptive conduct described herein.

630. Mallinckrodt marketed and sold Illinois in Alabama pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein.

631. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Illinois are persons under the Illinois Act. Each has been injured as a direct and proximate result of Mallinckrodt’s unconscionable, unfair, and deceptive conduct in violation of the Illinois Act, and each hereby seeks damages, through their representative Local 420.

**Kansas Unfair Trade and Consumer Protection,
Kan. Stat. § 50-623**

632. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, et seq.

633. Kan. Stat. § 50-626(a) states that [n]o supplier shall engage in any deceptive act or practice in connection with a consumer transaction; Kan. Stat. § 50-626(b): “[d]eceptive acts and practices include, but are not limited to, the following, each of which is hereby declared to be a violation of this act, whether or not any consumer has in fact been misled”: (3) “the will failure to state a material fact, or the willful concealment, suppression or omission of a material fact”; (7) “making false or misleading representations, knowingly or with reason to know, of fact concerning the reason for, existence of or amounts of price reductions, or the price in comparison to prices of competitors or one’s own price at a past or future time”; (8) “falsely stating, knowingly or with reason to know, that a consumer transaction involves consumer rights, remedies or obligations”.

634. Under Kan. Stat. § 50-627(a), “[u]nconscionable acts and practices, [n]o supplier shall engage in any unconscionable act or practice in connection with a consumer transaction. An unconscionable act or practice violates this act whether it occurs before, during or after the transaction.”

635. Kan. Stat. § 50-627(b)(1) states that “[t]he supplier took advantage of the inability of the consumer reasonably to protect the consumer's interests because of the consumer's physical infirmity, ignorance, illiteracy, inability to understand the language of an agreement or similar factor”.

636. Kan. Stat. § 50-627(b)(2) states that “when the consumer transaction was entered into, the price grossly exceeded the price at which similar property or services were readily obtainable in similar transactions by similar consumers.”

637. Kan. Stat. § 50-627(b)(5) “the transaction the supplier induced the consumer to enter into was excessively one sided in favor of the supplier”.

638. Kan. Stat. § 50-627(b)(6) “the supplier made a misleading statement of opinion on which the consumer was likely to rely to the consumer’s detriment.”

639. The unconscionable, unfair and deceptive acts and practices described herein are declared unlawful under the Kansas law.

640. Kansas authorizes any person, including “a natural person, corporation, ... ” to seek an injunction, damages, costs, and reasonable attorneys’ fees to prevent and remedy the unfair and deceptive conduct described herein.

641. Mallinckrodt marketed and sold Acthar in Kansas pursuant to the marketing and sales scheme alleged, at the inflated prices set forth herein.

642. Members of Plaintiff Class who purchased and/or reimbursed the cost of Acthar at these inflated prices in Kansas are persons under the Kansas Act. Each has been injured as a direct and proximate result of Mallinckrodt's unconscionable, unfair, and deceptive conduct in violation of the Kansas Act, and each hereby seeks damages, through their representative Local 420.

**Kentucky Revised Statutes,
Consumer Protection - Ky. Rev. Stat. § 367.110, et seq.**

643. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, et seq.

644. Under Ky. Rev. Stat. § 367.170(1) “[u]nfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful; (2) [f]or the purposes of this section, unfair shall be construed to mean unconscionable.”

645. Ky. Rev. Stat. § 367.175(2) “[i]t shall be unlawful for any person or person to monopolize, or attempt to monopolize or combine or conspire with any other person or persons to monopolize any part of the trade or commerce in this Commonwealth.”

**Louisiana Revised Statutes – Unfair Trade Practices and Consumer Protection Law
La. Rev. Stat. § 51:1401, et seq**

646. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, et seq.

647. Under La. Rev. Stat. § 51:1405(A) “[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful.”

**Maine Unfair Trade Practices Act,
5 Me. Rev. Stat. § 207, *et seq***

648. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq*.

649. 5 Me. Rev. Stat. § 207 “Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are declared unlawful.” 5 Me. Rev. Stat. § 207(1) “[T]he courts will be guided by the interpretations given by the Federal Trade Commission and the Federal Courts to Section 45(a)(1) of the Federal Trade Commission Act (15 United States Code 45(a)(1))...”.

**Maryland Consumer Protection Act,
Md. Com. Law Code § 13-101, *et seq***

650. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq*.

651. Maryland Unfair or deceptive trade practices include “[f]alse, falsely disparaging, or misleading oral or written statement, visual description, or other representation of any kind which has the capacity, tendency, or effect of deceiving or misleading consumers”. Md. Com. Law Code § 13-301(1). Any representation “fail[ing] to state a material fact if the failure deceives or tends to deceive” is unlawful. Md. Com. Law Code § 13-301(3).

652. “A price in comparison to price of a competitor or to one’s own price at a past or future time”. Md. Com. Law Code § 13-301(6)(ii).

653. Md. Com. Law Code § 13-301(9) “Deception, fraud, false pretense, false premise, misrepresentation, or knowing concealment, suppression, or omission of any material fact with the intent that consumer rely on the same in connection with (i) [t]he promotion or sale of any consumer goods, consumer realty or consumer service”.

**Massachusetts Consumer Protection Act (“MCPA”)
Mass. Gen. L. Ch. 93A, et seq.**

654. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, et. seq. (“MCPA”).

655. The MCPA regulates trade and commerce “directly or indirectly affecting the people of this commonwealth.” Mass. Gen. L. Ch. 93A § 9(1).

656. Under the MCPA, “[a]ny person, who has been injured by another person’s use or employment of any method, act or practice” that constitutes “[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce.” Mass. Gen. L. Ch. 93A §§ 2, 9(1). MCPA § 2(b) provides that these terms are interpreted consistent with Section 5 of the FTC Act (15 U.S.C. § 45(a)), which also prohibits “[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce.” Mass. Gen. L. Ch. 93A § 2(b); 15 U.S. § 45(a)(1).

657. Defendants’ conduct constitutes an unfair method of competition and unfair and deceptive acts or practices because Defendants’ conduct cause Plaintiff and the Class to pay artificially inflated prices for Acthar.

658. Mallinckrodt sold Acthar in Massachusetts under the circumstances and conditions described in this Complaint, and its conduct had a direct and substantial impact on trade and commerce in Massachusetts. Accordingly, such conduct falls within the prohibitions in Ch. 93A § 2.

659. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, et seq.

**Michigan,
Mich. Stat. § 445.901, et seq.**

660. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, et seq.

661. Mich. Stat. § 445.901, et seq.

Minnesota
Minn. Stat. § 8.31, et seq.

662. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 8.31, et seq.

Missouri Merchandising Practices Act (“MMPA”),
Mo. Rev. Stat. 407.020

663. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of the Missouri Merchandising Practices Act (“MMPA”), Mo. Rev. Stat. 407.020.

664. Under Section 407.020, the MMPA prohibits “[t]he act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce.” Mo. Rev. Stat. 407.020.

665. The Missouri Attorney General has defined an “unfair practice” as:

any practice which . . . [o]ffends any public policy as it has been established by the Constitution, statutes or common law of this state, or by the Federal Trade Commission, or its interpretive decisions; or . . . [i]s unethical, oppressive, or unscrupulous; and . . . [p]resents a risk of, or causes, substantial injury to consumers.

Mo. Att’y Gen. Reg., 15 CSR 60-8.02.

666. Mallinckrodt’s conduct constitutes an unfair method of competition and unfair and deceptive acts or practices because Mallinckrodt’s conduct caused Plaintiff and the Class to pay artificially inflated prices for Acthar.

**Montana,
Mont. Code § 30, 14-101, *et seq.***

667. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30, 14-101, *et seq.*

**Nebraska,
Rev. Stat. § 59-1601, *et seq.***

668. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*

**Nevada,
Nev. Rev. Stat. § 598.0903, *et seq.***

669. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*

**New Hampshire,
N.H. Rev. Stat. § 358-A:1, *et seq.***

670. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*

**New Mexico,
N.M. Stat. § 57-12-1, *et seq.***

671. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. § 57-12-1, *et seq.*

**New York (“Donnelly Act”),
N.Y. Gen. Bus. Law § 349 *et seq.***

672. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349 *et seq.*

**North Carolina (“Chapter 75”),
N.C. Gen. Stat. § 75-1.1, *et seq.***

673. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, et seq.

North Dakota,
N.D. Cent. Code § 51-15-01, *et seq.*

674. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, et seq.

Ohio,
Ohio Rev. Stat. § 1345.01, et seq.

675. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, et seq.

676. Dr. Mandel lives and works in Ohio, along with Mallinckrodt's Chris Sender. The acts and omissions of Dr. Mandel and Mallinckrodt described herein, in addition to those described in the Franks Complaint, demonstrate multiple violations of Ohio law.

Oklahoma
Okla. Stat. 15 § 751, et seq.

677. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of Okla. Stat. 15 § 751, et seq.

Oregon
Or. Rev. Stat. § 646.605, et seq.

678. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, et seq.

Rhode Island
R.I. Gen. Laws § 6-13.1-1, et seq.

679. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws § 6-13.1-1, et seq.

South Carolina

S.C. Code Laws § 39-5-10, *et seq.*

680. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*

**South Dakota
S.D. Code Laws § 37-24- 1, *et seq.***

681. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24- 1, *et seq.*

**Tennessee
Tenn. Code § 47-18-101, *et seq.***

682. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*

**Texas
Tex. Bus. & Com. Code § 17.41, *et seq.***

683. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*

**Utah
Utah Code § 13-11-1, *et seq.***

684. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code § 13-11-1, *et seq.*

Vermont’s Consumer Fraud Act (“Vermont CFA”), Vt. Stat. Ann. tit. 9, § 2451

685. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of 9 Vt. § 2451, *et seq.*

686. The express statutory purpose of the Vermont CFA is to “protect the public” against “unfair or deceptive acts or practices.” Vt. Stat. Ann. tit. 9, § 2451. Its purpose is remedial, and as such the court applies the Act liberally to accomplish its purposes.

687. To establish a “deceptive act or practice” under the Vermont CFA requires three elements: (1) there must be a representation, omission, or practice likely to mislead consumers; (2) the consumer must be interpreting the message reasonably under the circumstances; and (3) the misleading effects must be material, that is, likely to affect the consumer's conduct or decision regarding the product. Vt. Stat. Ann. tit. 9, § 2453(a).

688. Deception is measured by an objective standard, looking to whether the representation or omission had the “capacity or tendency to deceive” a reasonable consumer; actual injury need not be shown. To be reasonable, moreover, the consumer’s understanding need not be the only one possible; “if an ad conveys more than one meaning to reasonable consumers and one of those meanings is false, that ad may be condemned.” Furthermore, the Act “does not require a showing of intent to mislead, but only an intent to publish the statement challenged.”

689. Materiality is also generally measured by an objective standard, premised on what a reasonable person would regard as important in making a decision; it may include a subjective test, however, where the seller knows that the consumer, because of some peculiarity, is particularly susceptible to an omission or misrepresentation.

690. Where the seller knew, or should have known, that an ordinary consumer would need omitted information to evaluate the product or service, or that the claim was false, materiality will be presumed because the manufacturer intended the information or omission to have an effect.

Virginia
Va. Code § 59.1-196, et seq.

691. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, et seq.

Washington
Wash. Rev. Code § 19.86.010, et seq

692. Mallinckrodt has engaged in unfair competition or unfair, deceptive or fraudulent acts or practices in violation of Wash. Rev. Code § 19.86.010, et seq.

West Virginia
West Virginia Code § 46A-6-101, et seq.

693. Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of West Virginia Code § 46A-6-101, et seq.

WHEREFORE, Steamfitters Local Union No. 420 demands that judgment be entered in its favor and against Mallinckrodt in an amount to be determined at trial, under the consumer fraud laws of these states, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

COUNT V
NEGLIGENT MISREPRESENTATION

694. Plaintiff hereby incorporates by reference the preceding and following averments as if fully set forth herein and further alleges as follows.

695. Defendants' acts violate Pennsylvania common law against negligent misrepresentation, as well as the common law of negligence of other states where members of the Class reside.

696. Negligent misrepresentation requires proof of (1) a misrepresentation of a material fact; (2) made under circumstances in which the misrepresenter ought to have known of its falsity; (3) with an intent to induce another to act on it; and (4) which results in injury to a party acting in justifiable reliance on the misrepresentation.

697. Defendants made misrepresentations of material fact, as detailed herein. For instance, in setting and communicating the AWP-based prices for Acthar, which prices Local

420 paid, the Defendants made material misrepresentations that those prices represented a calculation of real and fact-based prices for their drugs, and that they represented the actual value of the product in the marketplace. Defendants called these prices “average wholesale prices” and when they knew they were not. They did so intending to induce Plaintiff and members of the Class to pay such “average wholesale prices” for Acthar, and Local 420 and the Class in fact, justifiably relied upon such prices in paying them.

698. As set forth herein, Mallinckrodt made multiple misrepresentations about the value of Acthar, in relation to the high prices it set for Acthar. Mallinckrodt knew that these representations were false, yet they made them intending to induce payors like Plaintiff and the Class to pay for Acthar. Plaintiff and the Class, in fact, justifiably relied on such statements of value, as Acthar was placed on lists of “specialty” drugs, by pharmacy benefits managers, like Future Scripts, for which deep discounts on brands and generics were unavailable.

699. These representations were material to the transactions at hand in that Local 420 used and relied upon the inflated prices for Acthar as the basis for the amount to pay and/or reimburse for Acthar under the specialty drug provisions of its agreements with IBC and Future Scripts.

700. Defendants knew or should have known of the falsity of their misrepresentations, especially as to the purported value of Acthar. Mallinckrodt bought Acthar for \$100,000 when it was selling for only \$40. Having spoken about the purported value of Acthar in relation to its high pricing Mallinckrodt and its KOLs had a duty to speak the truth about the lack of value for new indications.

701. As set forth more fully above, the prices communicated by Defendants to payors like Plaintiff through the ASAP and UBC HUB were artificial prices, unrelated to any actual,

reasonable price in the marketplace, or actual value of Acthar. Instead, they were intentionally created and manipulated by the Defendants for the purpose of generating exorbitant revenue, thus constituting false representations which the Defendants knew or, in the absence of recklessness, should have known to be false.

702. The Defendants made these misrepresentations about the actual prices for and value of Acthar with the intent of misleading Local 420 and the Class into relying on the prices as real and fact-based prices, rather than artificially inflated prices.

703. Local 420 and the Class justifiably relied upon these false misrepresentations in purchasing and/or reimbursing Acthar at the amount charged by Mallinckrodt through its ASAP and HUB based on the prices it set in 2007 and beyond. As a result, Plaintiff was injured by paying more for Acthar than it should have.

704. The Pennsylvania Supreme Court has expressly adopted several aspects of the Restatement (Second) of Torts relevant to the claims of Plaintiff and the Class. For instance, Section 552, which is titled “Information Negligently Supplied for the Guidance of Others”, provides, in pertinent part: (1) one who, in the course of his business, profession, or employment, or in any other transaction in which he has a pecuniary interest, supplies false information for the guidance of others in their business transactions, is subject to liability for pecuniary loss caused to them by their justifiable reliance upon the information, if he fails to exercise reasonable care or competence in obtaining or communicating the information. (2) ...[T]he liability stated in (1) is limited to loss suffered (a) by the person or one of a limited group of persons for whose benefit and guidance he intends to supply the information or knows that the recipient intends to supply it; and (b) through reliance upon it in a transaction that he intends the information to influence or

knows that the recipient so intends or in a substantially similar transaction.” *Bitt-Rite Contrs, Inc., v. Architectural Studio*, 581 Pa. 454, 459 n.1, 866 A.2d. 270 (2005).

705. Here, Mallinckrodt and UBC are “expert suppliers of information” about Acthar which information is widely disseminated to the public in general, and the medical community in particular, in order to induce justifiable reliance on the information being supplied. They hold themselves out to the public as such experts. Mallinckrodt is the manufacturer of Acthar, and an expert to whom patients (like the Plaintiff’s-beneficiary who took Acthar), payers (like Plaintiff and the Class), doctors (like the prescribers of the Acthar here), PBMs (like Express Scripts) and others look for information about value, pricing and safety of its drugs.

706. UBC is a self-described “HUB” of information about Acthar, its uses, benefits and prices. It is the Mallinckrodt’s designated interface between the providers, patients, and third party payors, as well as the manufacturer. Mallinckrodt trains UBC RSs about Acthar, which information UBC then shares with patients, payors and providers.

707. Mallinckrodt and UBC supplied information described herein “in the course of [their] business, profession, or employment”. They supplied misleading and deceptive information for the guidance of the Local 420 patients and the Plaintiff itself, as well as the Class, in course of business transactions involving the distribution, sales and payment for Acthar. Plaintiff and the Class justifiably relied on such information in paying the high prices for Acthar being charged in 2018.

708. Mallinckrodt and UBC failed to exercise reasonable care or competence in the promulgation of misleading and deceptive information about the value of Acthar, as evidenced by Express Scripts’ 2017 revelations that Acthar was not worth what was being charged for it. Plaintiff and the Class are entitled to recover for their losses suffered, since Local 420 and its

beneficiary, as well as the Class of third party payors, are persons for whose benefit and guidance Defendants intended to supply the information of Acthar value and the Defendants knew or should have known Local 420 and its beneficiary, as well as the Class, would receive such information and rely upon it.

709. As a direct and proximate result of the misrepresentations of Mallinckrodt, as set forth above, Local 420 and the Class were harmed in that they justifiably relied on the negligent misrepresentations about the value of Acthar in relation to its high prices.

710. Plaintiff and the Class were unaware of the artificial, inflated prices of Acthar, and would not have paid and/or reimbursed the artificially inflated prices for Acthar had they known of the misrepresentations of material fact made by Defendants. Plaintiff and the Class overpaid for the Acthar because of such misrepresentations.

WHEREFORE, Steamfitters Local Union No. 420 demands that judgment be entered in its favor, and in favor of the Class, and against Defendants, in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

COUNT VI
AIDING AND ABETTING/CONSPIRACY

711. Plaintiff hereby incorporates by reference the preceding and following averments as if fully set forth herein and further alleges as follows.

712. As set forth more fully above, beginning at least as early as 2007, the exact date being unknown to the Plaintiff and the Class, and continuing thereafter until the present, Defendants and other unnamed co-conspirators (including providers who acted as KOLs for Defendants), between and among themselves and others, entered into an agreement and/or otherwise engaged in a continuing conspiracy to defraud and deceive the Plaintiff and the Class

by causing it to pay more for Acthar than it otherwise would have paid in the absence of the Defendants' conspiracy and concerted action.

713. Pursuant to the unfair and deceptive schemes to distribute, price and market Acthar at high prices, which bore no reasonable relation to the value of the drug as ascribed to it in 2017 by Express Scripts, and the conspiracy alleged herein, and in furtherance thereof, Defendants and their co-conspirators engaged in a wide range of activities, the purpose and effect of which was to defraud, deceive and misinform Local 420 and the Class as to the truth about Acthar pricing and value, and acted or took substantial steps in furtherance of the conspiracy. Those acts include the following:

- a. discussing and agreeing among themselves and with their co-conspirators that they would control and communicate the price at which Local 420 and the Class paid for Acthar far above the reasonable value of the drug;
- b. discussing and agreeing among themselves and with their co-conspirators that they would increase the price at which Local 420 and the Class paid for Acthar;
- c. discussing and agreeing among themselves and with their co-conspirators that they would jointly implement and directly control the ASAP program, and associated materials and website, which enrolled patients into an exclusive distribution network for the administration of Acthar, allowing Defendants to raise the prices unchecked and to conduct their unfair pricing scheme for Acthar;
- d. discussing and agreeing among themselves and with their co-conspirators that they would directly control the exclusive distribution network for Acthar through the ASAP Program and the UBC "HUB",
- e. discussing and agreeing among themselves and with their co-conspirators that they would rely on employees to promote the ASAP Program through the marketing alleged herein;
- f. discussing and agreeing among themselves and with their co-conspirators that they would conceal and suppress the truth about the Acthar inflated prices, the Acthar true value, and the monies

earned from payors like Local 420 and the Class.

714. In addition to the specific facts set forth above, it is alleged the Defendants and their co-conspirators engaged in conspiratorial meetings, among the purposes of which meetings were to discuss the importance of controlling the direct distribution, marketing, sale and administration of Acthar to payors like Local 420 and the Class, and deriving substantial profits from these activities. These meetings took place in the summer of 2007, when Defendants were negotiating the contracts that form their exclusive agreement. The meetings and communications continued thereafter when Mallinckrodt and UBC agreed to raise the prices for Acthar to its current exorbitant levels, and communicate those inflated prices to patients and TPPs. They have also taken place after Relators sued.

715. There was a common design pursuant to which Defendants carried out their tortious acts of negligently misrepresenting the truth about Acthar, and the acts or practices in violation of the consumer fraud laws. The common designed involved, among other things, misleading patients and payors, like Plaintiff and the Class, about the value of Acthar in relation to its high prices, and concealing the truth about Acthar and their exclusive arrangements.

716. There was a common design pursuant to which Defendants carried out their tortious acts of negligently misrepresenting the truth about Acthar and their exclusive arrangements, and the acts or practices in violation of the consumer fraud laws. The common design involved, among other things, misleading patients and payors, like Plaintiff and the Class, about the value of Acthar in relation to its high prices, and concealing the truth about Acthar and their exclusive arrangements.

717. Here, Mallinckrodt aided and abetted its sales representatives, including MSLs, and multiple doctors engaged as KOLs in unlawful acts, practices, misrepresentations, omissions

and deception, knowing that they were breaching their duty to tell the truth, having spoken publicly about Acthar, its uses and benefits, and its price. Mallinckrodt aided and abetted providers in breaching their obligations to patients covered by Plaintiff and the Class by continuing to conceal and suppress the truth about Acthar's lack of value. Mallinckrodt gave substantial assistance to sales representatives and KOLs in accomplishing their tortious conduct, and their conduct in so assisting, breached a separate duty owed to the Plaintiff and the Class.

718. UBC aided and abetted Mallinckrodt in their schemes by serving as the HUB and direct interface with patients and payors to ensure that Acthar prescriptions were filled and paid for at inflated AWP as set by Mallinckrodt.

719. The Defendants performed the conspiratorial acts set forth herein intending to injure payors of Acthar, like Local 420 and the Class, by causing them to pay inflated prices so that the Defendants could derive substantial profits.

720. The Defendants performed the acts alleged herein in furtherance of the common plan or design for the conspiracy with intent and/or with knowledge of the injury and damage it would cause to Local 420 and the Class, and with knowledge and intent to cause such injuries and/or with reckless disregard for the consequences. These acts were either unlawful (as in the case of the acts described in Counts I, II and III) or lawful by an unlawful means as for an unlawful purpose (as in the case of Defendants' willful silence in the face of its co-conspirators' misinformation and misrepresentations).

721. As a direct and proximate result of the Defendants' conspiracy and aiding and abetting as alleged herein, Local 420 and the Class have been injured and damaged, and the Defendants are jointly and severally liable for such injuries and damages.

WHEREFORE, Steamfitters Local Union No. 420 demands that judgment be entered in

its favor, and in favor of the Class and against Defendants, in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

COUNT VII
UNJUST ENRICHMENT

722. Plaintiff hereby incorporates by reference the preceding and following averments as if fully set forth herein and further alleges as follows.

723. This Count alleges unjust enrichment against Mallinckrodt.

724. Like the beneficiaries in the Class, Local 420's covered beneficiary received direct shipments of Acthar from Mallinckrodt via its exclusive distribution mechanism established with CuraScript and UBC. In exchange for such Acthar, Local 420 and the Class made payments to Mallinckrodt, through UBC. The amount charged by Mallinckrodt for Acthar was the amount paid by Local 420 and the Class pursuant to their agreements with their healthcare plans.

725. The amounts paid by Local 420 and the Class were valuable to Mallinckrodt and UBC, and both Mallinckrodt and UBC were unjustly enriched by such payments, in that, the reimbursement rates charged by Mallinckrodt were valuable and beneficial to Mallinckrodt, and Mallinckrodt compensated UBC out of such funds.

726. By engaging in the conduct described herein, Mallinckrodt and UBC have knowingly obtained benefits from Local 420 and the Class, namely, grossly inflated revenue from their direct involvement in coordinating all aspects of the receipt of and payments for Acthar, under circumstances such that it would be inequitable and unjust for Mallinckrodt and UBC to retain such benefits.

727. Mallinckrodt and UBC were able to extract exorbitant revenue from Local 420 and the Class beyond what either could have received in the absence of their unlawful conduct. This conduct violated the consumer protection laws of Pennsylvania and other states, as well as the common laws of Pennsylvania and other states, and, as such, interfered with the legally protected interests of Local 420 and the Class.

728. Local 420 and each member of the Class are therefore entitled to an award of compensatory damages in an amount to be determined at trial, or the imposition of a constructive trust upon the monies derived by the Defendants by means of the above-described actions.

729. By engaging in the unlawful conduct described herein, Mallinckrodt and UBC have been knowingly enriched by the amount charged for Acthar over and above what they could have charged in a competitive market.

WHEREFORE, Steamfitters Local Union No. 420 demands that judgment be entered in its favor, and in favor of the Class, and against Mallinckrodt, in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

COUNT VIII
DECLARATORY AND INJUNCTIVE RELIEF

730. Plaintiff hereby incorporates by reference the preceding and following averments as if fully set forth herein and further alleges as follows.

731. Plaintiff has alleged an interest which, insofar as it paid inflated prices for Acthar, is substantial and immediate insofar as it has had to pay exorbitant prices for Acthar in 2018. There is a reasonable likelihood that Plaintiff will have to pay for Acthar in the future, especially given Mallinckrodt's and UBC's marketing efforts to expand Acthar prescriptions into new indications, like the rheumatic disorder suffered by its beneficiary.

732. Thus, Plaintiff has alleged a real, actual controversy with Defendants that requires immediate attention. The public has already shown an interest in the Acthar lawsuit being litigated in Rockford, Illinois. Thus, Plaintiff's request for declaratory and injunctive relief does not seek merely an abstract or advisory opinion.

733. Plaintiff and the Class hereby request that the acts and practices set forth herein be declared unlawful under the consumer fraud laws and/or the common law of negligent misrepresentation, regardless of the quantum of damages suffered individually by Plaintiff and the Class, the precise calculation of which will have to await discovery. This will inure to the benefit of Plaintiff, its beneficiaries, the members of the coalition of which Plaintiff is a part, and self-funded payors, everywhere in the Class who have paid, are paying, or will pay in the future for Acthar.

734. Plaintiff and the Class also request the issuance of an injunction to enjoin Mallinckrodt and UBC from conspiring and agreeing to raise the prices of Acthar above competitive levels, and from charging such inflated prices. The injunction should also prohibit Mallinckrodt and UBC from engaging in the unlawful practices alleged herein.

735. An injunction is needed to prevent immediate and irreparable harm that cannot be compensated adequately by damages. Plaintiff and the Class will be irreparably harmed if an injunction does not timely issue because patients are put at risk as payors like Plaintiff and the Class are forced to decide about whether to cover all the new indications for which Mallinckrodt and UBC are marketing Acthar. Further, because multiple, individual actions would be required to bring about what one injunction in this action could accomplish, there is an inadequate legal remedy. Plaintiff has no adequate remedy at law to prevent Defendants from furthering acting to

harm itself and its patient-beneficiaries due to the unchecked nature of their pricing decisions, which have been demonstrated to be far above any reasonable “value” assessment.

736. Greater injury would result from refusing the injunction than from granting it, as patients and payors like Plaintiff will continue to be threatened by new prescriptions of Acthar at exorbitant price levels, threatening patient care. The issuance of an injunction will not substantially harm Mallinckrodt or UBC, because Mallinckrodt and UBC will continue to sell Acthar for all the approved indications, albeit at lower prices.

737. The injunction will properly restore the parties to where they were before the unlawful conduct was begun by Defendants.

738. Plaintiff has a clear right to relief and is likely to prevail on the merits, which this case is related to and which at least Mallinckrodt has indicated a willingness to settle rather than fight.

739. The injunction, as will be framed in an appropriate motion to the court, will be reasonably suited to abate the offending activity only.

740. The public interest will not be adversely affected by the injunction. To the contrary, the public interest will be served by stopping the unlawful practices by Mallinckrodt.

741. All the requisite elements for issuance of an injunction have been, and will be, met.

PRAYER FOR RELIEF

WHEREFORE, Steamfitters Local Union No. 420 and the Class request the Court to enter the following relief:

- a. Declare unlawful the acts and practices alleged herein, enjoin Mallinckrodt from committing the acts alleged herein, and restore the status quo before the unlawful conduct took place;

- b. Enter judgment Mallinckrodt and UBC for the violations alleged herein;
- c. Certify a Class of all third party payors and their beneficiaries;
- d. Award the actual damages incurred by Plaintiff and the Class as a result of the wrongful acts complained of, along with pre-judgment and post-judgment interest at the maximum rate allowed by law;
- e. Award statutory damages set forth herein under the statutory claims alleged;
- f. Award treble damages or multiple damages by operation of law;
- g. Award punitive damages;
- h. Award Plaintiff and the Class the costs of this action, including reasonable attorney's fees, and, where applicable, expert fees; and
- i. Award such other and further relief as the Court may deem just and appropriate.

JURY DEMAND

Steamfitters Local Union No. 420 and the Class hereby demand a trial by jury of all issues so triable in this cause.

Respectfully submitted,

Date: July 12, 2019

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PLAINTIFF'S EXHIBIT "B"

**IN THE UNITED STATES DISTRICT COURT FOR
 THE EASTERN DISTRICT OF PENNSYLVANIA**

STEAMFITTERS LOCAL UNION NO.)	
420 ,)	
)	
Plaintiff,)	
v.)	No. 2:19-cv-03047-BMS
MALLINCKRODT ARD, INC., et al.,)	
Defendants.)	
)	

UNITED BIOSOURCE CORPORATION’S MOTION TO DISMISS COMPLAINT

Defendant United BioSource Corporation, by and through its counsel, Walsh Pancio LLC and Quinn Emanuel Urquhart & Sullivan, LLP, hereby moves to dismiss Plaintiff’s Complaint (ECF No. 1) pursuant to Federal Rule of Civil Procedure 12(b)(6) for the reasons set forth in detail in the accompanying Memorandum of Law.

WHEREFORE, Defendant respectfully requests that this Court grant its Motion to Dismiss Plaintiff’s Complaint with prejudice.

Dated: August 20, 2019

Respectfully submitted,

/s/ Joseph P. Walsh

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**IN THE UNITED STATES DISTRICT COURT FOR
THE EASTERN DISTRICT OF PENNSYLVANIA**

STEAMFITTERS LOCAL UNION NO.
420 ,

Plaintiff,

V.

MALLINCKRODT ARD, INC., et al.,
Defendants.

No. 2:19-cv-03047-BMS

**MEMORANDUM OF LAW IN SUPPORT OF UNITED
BIOSOURCE CORPORATION'S MOTION TO DISMISS COMPLAINT**

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Defendant United BioSource Corporation (“UBC”) respectfully submits this Memorandum of Law in support of its Motion to Dismiss the Complaint for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6).

PRELIMINARY STATEMENT

Plaintiff’s lawsuit is merely a copycat of allegations substantially similar to claims already dismissed in another lawsuit (the “*Rockford* Litigation”¹). Plaintiff’s counsel filed the *Rockford* Litigation on behalf of a putative class that already includes all the members of the putative class asserted here, and raises essentially the same arguments.² Specifically, as in the *Rockford* Litigation, Plaintiff’s grievance arises from Defendant Mallinckrodt’s³ pricing of the prescription medication Acthar. The *Rockford* court already dismissed the RICO and fraud claims that Plaintiff’s counsel asserted there based on substantially similar allegations. The same result is appropriate here for similar reasons.

First, Plaintiff’s RICO claims (Counts I–II) fail because Plaintiff does not identify any misrepresentation by UBC—let alone plead one with the particularity required by Rule 9(b). The RICO claims also should be dismissed because Plaintiff does not sufficiently allege that UBC participated in any RICO enterprise. In particular, Plaintiff does not allege that UBC’s participation was required to effectuate the alleged price inflation. Plaintiff instead concedes that

¹ *City of Rockford v. Mallinckrodt ARD, Inc.*, No. 17-cv-50107 (N.D. Ill.). Defendants have moved to transfer this litigation to the Northern District of Illinois under the first-to-file rule and 28 U.S.C. § 1404. Notably, another overlapping lawsuit filed by different counsel on behalf of a different plaintiff has already been transferred to the *Rockford* court on these grounds. See *MSP Recovery Claims, Series LLC et al. v. Mallinckrodt ARD Inc. et al.*, No. 17-7928, Order on Defendants’ Motion to Transfer (C.D. Cal. Jan. 17, 2018) [Dkt. No. 53].

² In addition to the *Rockford* Litigation, Plaintiff’s counsel also has now filed three other copycat lawsuits against UBC: *International Union of Operating Engineers Local 542 v. Mallinckrodt ARD, Inc. et al.*, No. 2018-14059 (Pa. Ct. Com. Pl. [Montgomery County]); *Washington County Board of Education v. Mallinckrodt ARD, Inc., et al.*, No. 1:19-cv-01854-JKB (D. Md.); and *Acument Global Technologies, Inc. v. Mallinckrodt ARD, Inc., et al.*, No. CT-2275-19 (Tenn. Cir.).

³ This brief refers to Mallinckrodt ARD, Inc. and Mallinckrodt plc collectively as “Mallinckrodt.”

Mallinckrodt had unchecked power to control Acthar's pricing on its own. That concession necessarily precludes any alleged injury caused by UBC. Indeed, Plaintiff's only causation allegations as to UBC (that the purported misrepresentations somehow caused it to decide to pay for its beneficiaries' Acthar prescriptions) are conclusory on their face and belied by other allegations that it included Acthar after much of the alleged fraud was public and may do so again in the future. Finally, any alleged injury due to paying inflated prices requires dismissal under the indirect purchaser rule.

Second, Plaintiff's Unfair Trade Practices and Consumer Protection Law ("UTPCPL") and negligent misrepresentation claims (Counts III, V) fail because Plaintiff has not specifically alleged any fraudulent or deceptive conduct by UBC, or any specific statements that UBC should or could have realized were false. For these claims, Plaintiff relies exclusively on statements that either were not deceptive or allegedly made by individuals and entities other than UBC. Plaintiff's conclusory assertions that any purportedly false statements can nevertheless somehow be attributed to UBC do not meet even Rule 8's plausibility standard. These claims also fail because the Complaint does not sufficiently allege that Plaintiff relied on any statements from UBC before deciding to pay for its beneficiaries' Acthar prescriptions. And like the RICO claims, any allegations of such reliance are belied by Plaintiff's admission that it paid for and may continue to pay for Acthar again despite knowing at least much of the alleged fraud.

Third, Plaintiff's class claims under other state consumer protection laws (Count IV) should be dismissed because Plaintiff's class allegations and class claims are all directed at Mallinckrodt. There are no specific allegations as to UBC or that UBC violated any specific state law.

Fourth, Plaintiff's claims for aiding and abetting fraud or conspiracy to commit fraud

(Count VI) also fail for multiple independent reasons. As an initial matter, Pennsylvania law does not recognize any cause of action for aiding and abetting fraud. Even if it did, that claim would fail, along with any equivalent conspiracy claim, because Plaintiff has failed to sufficiently allege any underlying fraud or that UBC agreed to enter into any fraudulent conspiracy.

Fifth, Plaintiff's claim for unjust enrichment (Count VII) fails because the Complaint does not allege that Plaintiff conferred any benefit on UBC, or that UBC received or retained any such benefit. The Complaint instead alleges that the claimed benefit—payments for Acthar—was conferred on Mallinckrodt, not UBC. Further, because the unjust enrichment claim is pled as a companion to Plaintiff's misrepresentation claims, the deficiencies in those underlying claims are fatal to the unjust enrichment claim as well.

Sixth, Plaintiff's claim for declaratory and injunctive relief (Count VIII) must fail because those claims are derivative of the substantive claims and accordingly fall with them. Further, Plaintiff's allegations as to future injury are entirely speculative. Plaintiff may stop covering Acthar prescriptions at any time and therefore does not need Court intervention.

RELEVANT FACTUAL ALLEGATIONS

A. Mallinckrodt's Alleged Distribution, Pricing, and Promotion of Acthar

Mallinckrodt manufactures, markets, distributes, and sells Acthar. (Compl. ¶ 2.) Plaintiff contends that Mallinckrodt acquired Acthar in July 2001, when Mallinckrodt (formerly Questcor Pharmaceuticals, Inc.) ("Questcor") purchased Acthar from Aventis Pharmaceutical Products Inc. (*Id.* ¶¶ 1, 3.) Acthar is a "specialty pharmaceutical" injection containing adrenocorticotrophic hormone ("ACTH") distributed only through "specialty pharmacy distributors" and "specialty pharmacy providers." (*Id.* ¶¶ 4, 42.)

Acthar was approved by the FDA on April 29, 1952, for over 50 conditions, ranging from

alcoholism, poison ivy, and radiation sickness to nephrotic syndrome. (*Id.* ¶ 41.) It is approved today for 19 indications. (*Id.* ¶¶ 41, 97.) Acthar is alleged to be the “gold standard” only for treating infantile spasms, a serious condition in infants. (*Id.* ¶ 118.) For other indications, Plaintiff alleges that there are alternative treatments. (*Id.* ¶¶ 101–02, 106, 111.) Plaintiff nevertheless contends that, because Acthar was the “one, sole-source drug treatment” for infantile spasms, Mallinckrodt could take advantage of that allegedly “captive market” to charge “a much higher price” for Acthar. (*Id.* ¶¶ 153–54.) Plaintiff alleges that Mallinckrodt has raised the price of Acthar substantially since 2001. (*Id.* ¶ 178.)

Plaintiff contends that, in 2007, Mallinckrodt changed the way it distributed and sold Acthar by engaging UBC to act as its exclusive “HUB” of operations controlling both the distribution and reimbursement of Acthar directly with patients and third-party payors (“TPPs”). (*Id.* ¶ 8.) Plaintiff further contends that, also in 2007, Mallinckrodt and UBC adopted the “Acthar Support & Access Program” (“ASAP”) (*id.* ¶ 159), under which all Acthar prescriptions are routed through UBC to patients, and all Acthar payments are coordinated by UBC to Mallinckrodt (*id.* ¶ 160). Specifically, through ASAP, “UBC confirms the prescription by the provider and the associated specialty pharmacy, and then confirms the patient’s insurance coverage or other source of payment. UBC then arranges for the Acthar to be delivered directly to the patient by CuraScript.” (*Id.* ¶ 163.) To receive these services from UBC, the patient signs a form that authorizes “Mallinckrodt and its agents” to perform certain functions (*id.* ¶ 166 (quoting Compl. Ex. A)) including “reimbursement and coverage support, patient assistance and access programs, medication shipment tracking, and home injecting training” (*id.* ¶ 167 (quoting Compl. Ex. A)).

Also in 2007, Plaintiff alleges that Mallinckrodt created a new position within the

company called “Medical Science Liaisons” or “MSLs” to promote the sale of Acthar for unapproved uses and doses. (*Id.* ¶ 239). Plaintiff further alleges that Mallinckrodt has engaged “Key Opinion Leaders” or “KOLs” to disseminate clinical data about Acthar containing false and misleading statements about Acthar. (*Id.* ¶¶ 244–45).

B. Plaintiff’s Payments for Acthar

Plaintiff alleges that it provides a pharmacy benefit to its employees. (*Id.* ¶ 28.) According to the Complaint, “While IBC [Independence Blue Cross] coordinates [Plaintiff’s] prescription drug benefits, including specialty drugs like Acthar, through Future Scripts, a pharmacy benefits manager (‘PBM’), [Plaintiff] is self-funded, meaning that [Plaintiff] and its beneficiaries pay the full costs of drugs like Acthar.” (*Id.*) Plaintiff alleges that, in early 2018, it paid for four prescriptions of Acthar for the spouse of one of its members for the treatment of a rheumatic disorder. (*Id.* ¶ 29.) Plaintiff further alleges that it has not yet “decide[d] about whether to cover” Acthar prescriptions for “the new indications” for which Acthar is allegedly being marketed. (*Id.* ¶ 735.)

ARGUMENT

On a motion to dismiss under Rule 12(b)(6), “[a] court need not credit ‘bald assertions’ or ‘legal conclusions.’” *Renfro v. Unisys Corp.*, 2010 WL 1688540, at *2 (E.D. Pa. Apr. 26, 2010) (quoting *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997)), *aff’d*, 671 F.3d 314 (3d Cir. 2011). Instead, “the legal elements and factual allegations of the claim should be separated, with the well-pleaded facts accepted as true but the legal conclusions disregarded.” *Id.* at *3. Where the “court can only infer the mere possibility of misconduct, the complaint must be dismissed because it has alleged—but has failed to show—that the pleader is entitled to relief.” *Id.*

I. THE RICO CLAIMS (COUNTS I–II) SHOULD BE DISMISSED

Plaintiff's RICO claims should be dismissed as a matter of law. "In order to plead a violation of RICO [under Section 1962(c)], plaintiffs must allege (1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity." *Lum v. Bank of Am.*, 361 F.3d 217, 223 (3d Cir. 2004), *abrogated on other grounds by Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007). A plaintiff must further allege that the asserted scheme was both a "but for" and proximate cause of his alleged injury. *See Holmes v. Sec. Inv'r Prot. Corp.*, 503 U.S. 258, 268 (1992). The complaint fails to sufficiently allege each of these elements.

A. Plaintiff Fails the Racketeering Element: It Does Not Sufficiently Plead Any Predicate Act by UBC

Plaintiff here alleges racketeering activity based on predicate acts of purported mail and wire fraud. (*See* Compl. ¶¶ 493, 509.) Those predicates require "some sort of fraudulent misrepresentation or omission." *Lum*, 361 F.3d at 223. They also must be pled with particularity that "satisf[ies] the heightened pleading requirements of Federal Rule of Civil Procedure 9(b)." *Franks v. Food Ingredients Int'l, Inc.*, 2010 WL 3046416, at *4 (E.D. Pa. July 30, 2010) (citing *Warden v. McClelland*, 288 F.3d 105, 114 (3d Cir. 2002)). "To satisfy this standard, the plaintiff must plead or allege the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation." *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007) (citing *Lum*, 361 F.3d at 223–24). Plaintiff does not come close to meeting the Rule 9(b) heightened pleading standard for these claims. Indeed, the *Rockford* court already has dismissed the RICO claims asserted there for failure to describe the alleged fraud sufficiently to satisfy Rule 9(b). *Rockford v. Mallinckrodt ARD, Inc.*, 360 F. Supp. 3d 730, 774 (N.D. Ill. 2019) ("The [Second Amended Complaint] does not clarify what specifically was done over the internet and through the mail.").

Plaintiff bases its RICO claims on alleged misrepresentations as to Acthar's "safety,

efficacy, usefulness and value.” (Compl. ¶ 495.) But nowhere in its over 160-pages does Plaintiff’s Complaint point to a specific fraudulent representation made by UBC regarding any of those subjects (or any others). Rather, ***all*** the misrepresentations identified in the Complaint were made by ***entities other than UBC***. For instance, the Complaint alleges that Dr. Tumlin contracted with Mallinckrodt—not UBC—to develop and then disseminate purportedly misleading clinical data for Acthar. (Compl. ¶¶ 296–302.) Plaintiff alleges only vaguely that UBC was “trained with Dr. Tumlin’s studies” and “used them” in an unspecified manner (*id.* ¶ 305), but does not allege any facts suggesting that UBC was aware of Mallinckrodt’s allegedly improper relationship with Dr. Tumlin. To the contrary, Plaintiff alleges that knowledge of the details of that relationship “lies within the ***exclusive*** control of ***Mallinckrodt*** and Dr. Tumlin.” (*Id.* ¶ 311 (emphases added).)

Similarly, the Complaint alleges that Dr. Greenhouse—not UBC—wrote a fraudulent letter to appeal a coverage denial for Acthar. (*Id.* ¶¶ 377–83.) Plaintiff’s allegations that UBC, as an administrative hub, sent and then “forwarded” the purportedly misleading letter from Dr. Greenhouse are insufficient because Plaintiff does not allege that UBC knew any statements in the letter were false. (*Id.* ¶ 377.) Nor would any such allegations be plausible because Plaintiff also fails to plead any specific facts suggesting any such knowledge, particularly when it was Express Scripts—UBC’s then-owner—who issued the coverage denial that Dr. Greenhouse allegedly circumvented. (*Id.* ¶ 368; *see also id.* ¶ 5.) The Complaint does vaguely assert that UBC was “fully aware” that a different doctor, Dr. Mandel, made misrepresentations in unspecified “letters [that] were sent to UBC, to be used with [unspecified] TPP’s” (*id.* ¶¶ 285–87), but such allegations are insufficiently particular and similarly implausible. Indeed, in its one example for Dr. Mandel, Plaintiff makes no specific allegation regarding UBC’s knowledge—

another allegedly fraudulent letter sent to appeal another clinical denial by UBC's then-owner Express Scripts. (*Id.* ¶ 402.)

Plaintiff also alleges that “[i]t is believed and therefore averred” that two other doctors’ unidentified “patients and their TPP[s] were subjected to and harmed by” those doctors’ allegedly improper prescriptions of Acthar, for which UBC merely “coordinated the payment.” (*Id.* ¶¶ 314–15 (Dr. Clauser), ¶¶ 331, 333 (Dr. Urbaniak).) But Plaintiff does not identify any specific statement by either doctor that is alleged to be false or describe how UBC was specifically involved in any such statement; nor does Plaintiff allege that UBC was aware that any such specific statement was false.

Finally, and tellingly, Plaintiff resorts to editing excerpts from filings in a qui tam lawsuit to assert that UBC is somehow implicated by allegations that Mallinckrodt alone used the Acthar patient assistance program to improperly cover patient co-pays. Plaintiff asserts that “the government alleges” that “Mallinckrodt [and UBC] knew” and “intended” certain improper purposes for the Acthar patient support program. (*Id.* ¶ 412 (alteration in original).) But the government made those allegations against Mallinckrodt alone (*see id.* ¶ 15 (quoting, without alteration, the same paragraph from the U.S. Complaint)) and Plaintiff just added UBC to that allegation on its own. In fact, the U.S. Complaint does not even **mention** UBC's name. (*See* U.S. Compl.) Further, as with UBC's alleged transmission of Dr. Greenhouse's letters, Plaintiff does not plead any specific facts plausibly suggesting that UBC, as an administrative hub, coordinated the paperwork for that program with fraudulent intent.

As the above makes clear, there are no specific allegations against UBC sufficient to plead fraud allegations compliant with Rule 9(b). Instead and at best, Plaintiff's case against UBC rests solely on “general or ‘group’ pleading,” which this Court has previously held is “not

sufficient to maintain a cause of action under the requirements of Rule 9(b).” *Fleet Nat’l Bank v. Boyle*, 2005 WL 2455673, at *11 (E.D. Pa. Sept. 12, 2005) (dismissing fraud claim against subset of individual defendants who were “not alleged to have made any misrepresentations” themselves).

B. Plaintiff Fails to Satisfy RICO’s Enterprise Requirement

Plaintiff’s RICO claims also should be dismissed for failure to satisfy the RICO enterprise requirement. Section 1962(c) and (d) require plaintiffs to plausibly allege that a RICO defendant “conducted or participated in the conduct of the ‘*enterprise’s* affairs,’ not just [its] *own* affairs.” *Reves v. Ernst & Young*, 507 U.S. 170, 185 (1993) (emphases in original). A complaint does not plausibly suggest such “conduct” where “the activities the complaint describes are entirely consistent with [enterprise members] each going about [their] own business.” *United Food & Commercial Workers Unions v. Walgreen Co.*, 719 F.3d 849, 855–56 (7th Cir. 2013). Stripped of conclusory assertions, Plaintiff has alleged only that UBC provided services to Mallinckrodt by contracting to operate a central hub to streamline the coordination of patient services for Acthar. (See Compl. ¶ 163.) But merely “providing goods or services to an alleged RICO enterprise is insufficient to compel liability.” *In re Aetna UCR Litig.*, 2015 WL 3970168, at *28 (D.N.J. June 30, 2015).

Significantly, each of the three “schemes” that Plaintiff alleges as the “essential components” of the alleged RICO enterprises could have been accomplished by Mallinckrodt alone, with no assistance from UBC. First, Plaintiff alleges there was a “Distribution Scheme” in which Mallinckrodt allegedly “limited the distribution of Acthar from multiple distribution outlets to just one, CuraScript, and engaged UBC to act as its exclusive ‘HUB’ of operations.” (Compl. ¶ 8.) But exclusive distribution agreements are generally lawful precisely because they “provide[] no monopolistic benefit to [a monopolist] that it does not already enjoy and would not

continue to enjoy” absent any agreement. *E & L Consulting, Ltd. v. Doman Indus. Ltd.*, 472 F.3d 23, 29 (2d Cir. 2006); *see also Rutman Wine Co. v. E. & J. Gallo Winery*, 829 F.2d 729, 734–36 (9th Cir. 1987) (“[A]n agreement between a manufacturer and a distributor to establish an exclusive distributorship is not, standing alone, a violation of antitrust laws, and in most circumstances does not adversely affect competition in the market.”). In other words, the alleged “exclusive distribution arrangement” did nothing to enhance Mallinckrodt’s power “to raise the prices of Acthar.” (Compl. ¶ 8; *see also id.* ¶ 153 (stating Mallinckrodt leveraged market power as owner of the “one, sole-source drug treatment” for infantile spasms).)

Second, Plaintiff alleges a “Pricing Scheme” in which Mallinckrodt “inflated the prices paid by TPPs for Acthar.” (*Id.* ¶ 11.) Plaintiff asserts at points that “Mallinckrodt agreed with CuraScript and UBC to raise” those prices (*id.*), but such allegations are contradicted by Plaintiff’s later admissions that, for example, “Mallinckrodt knew that it could, and did directly, control and raise the [Average Wholesale Price] for Acthar at any time simply by forwarding to the pricing compendia a new and higher AWP.” (*Id.* ¶ 212; *see also id.* ¶ 19 (alleging damages “based on the inflated AWP prices set by **Mallinckrodt**” (emphasis added))). UBC’s alleged involvement was thus totally unnecessary for Mallinckrodt to effectuate the so-called “Pricing Scheme.”

Finally, Plaintiff alleges that “**Mallinckrodt** also embarked on a Marketing Scheme designed to incentivize sales of Acthar.” (*Id.* ¶ 16 (emphasis added).) According to the Complaint, “**Mallinckrodt** vastly expanded its direct-to-consumer selling” using “medical science liaisons” who convinced influential physicians to “deliver[] **Mallinckrodt’s** false, misleading and deceptive promotional messages about the safety, efficacy and value of Acthar.” (*Id.* ¶ 17 (emphasis added).) Tellingly, Plaintiff concedes that “[t]he Marketing Scheme in this

case is identical to the scheme alleged” in the qui tam lawsuits that, as discussed above, are brought against Mallinckrodt alone. (*Id.* ¶ 236; *see also id.* ¶ 13 (stating whistleblowers sued only Mallinckrodt).) Plaintiff does not plead any facts to suggest that UBC’s participation was required for Mallinckrodt to establish allegedly improper relationships with physicians. Instead, Plaintiff alleges just the opposite; specifically, that the details of the allegedly “unlawful white coat marketing scheme . . . lie within **Mallinckrodt’s** exclusive custody and control.” (*Id.* ¶ 277 (emphasis added).)

In short, the Complaint’s allegations establish that Mallinckrodt and UBC “achieved collectively nothing that would have been impossible to achieve” by Mallinckrodt without any culpable assistance. *See In re Aetna UCR Litig.*, 2015 WL 3970168, at *29. Allegations that UBC “coordinat[ed] all aspects of the scheme and conspiracy” (Compl. ¶ 39) are insufficient to satisfy the enterprise requirement when they “only describe[] how [UBC] conducted its otherwise legitimate business operations.” *In re Aetna UCR Litig.*, 2015 WL 3970168, at *30. Plaintiff therefore has failed to satisfy RICO’s enterprise requirement.

C. Plaintiff Fails to Allege How UBC’s Conduct Caused Injury

In addition to failing to allege predicate acts of fraud, Plaintiff also has failed to allege that UBC caused any alleged injury. To state a RICO claim, a plaintiff must allege that the asserted scheme was both a “but for” and proximate cause of his alleged injury. *Holmes v. Sec. Inv’r Prot. Corp.*, 503 U.S. at 268.

First, Plaintiff’s claimed injury—alleged overpayments based on “inflated AWP prices set by **Mallinckrodt**” (Compl. ¶ 19)—is too disconnected from any alleged conduct by UBC. The two thus lack the “direct relation” required to support proximate causation. *See Rockford*, 360 F. Supp. 3d at 775 (quoting *Hemi Grp., LLC v. City of New York*, 559 U.S. 1, 9 (2010) (plurality opinion)). Critically, the Complaint is replete with allegations that Mallinckrodt alone

“could, and did directly, control and raise the AWP for Acthar at any time simply by forwarding to the pricing compendia a new and higher AWP.” (Compl. ¶ 212; *see also id.* ¶ 156 (alleging Mallinckrodt’s ability to set price was “only limited by what Mallinckrodt predicted that payors, like Local 420, would be willing to bear”).) Plaintiff’s theory is that, if not for the alleged scheme, there **could** have been a “backlash from patients and payors” that, **if** it occurred, **could** have influenced the prices Mallinckrodt set. (*Id.* ¶ 12.) But as the *Rockford* court explained when dismissing substantially similar RICO claims, “the ‘general tendency’ in this context is for courts ‘not to go beyond the first step,’ because ‘multiple steps . . . separate the alleged fraud from the asserted injury.’” *Id.* (citation omitted) (citing *Hemi*, 559 U.S. at 10, 15).

Further, Plaintiff’s claimed injury of having “paid the inflated AWP” (*id.* ¶ 172) fail under the indirect purchaser rule. *In re Insulin Pricing Litig.*, 2019 WL 643709, at *11 (D.N.J. Feb. 15, 2019) (unpublished) (“[C]ourts may apply the indirect purchaser rule to RICO actions with the same force as under antitrust law”). This distinguishes Plaintiffs’ complaint from the *Avandia* litigation, upon which Plaintiffs are expected to rely. *In re Avandia Mktg., Sales Practices & Prod. Liab. Litig.*, 804 F.3d 633 (3d Cir. 2015). Specifically, in *In re Insulin*, the District of New Jersey distinguished the claims there, which were based on “allegedly fraudulent prices,” from the *Avandia* claims, which were based on “includ[ing] the product . . . in their formulary decisions.” *Id.* For the former and as Plaintiffs have alleged here, conclusory allegations that “benchmark prices [like AWP] ‘directly’ affect the price paid by consumers” are “insufficient to overcome the indirect purchaser rule,” which “still applies even when the alleged improper price inflation is passed to a plaintiff on a ‘dollar for dollar basis.’” *In re Insulin*, 2019 WL 643709, at *12 (citing *McCarthy v. Recordex Serv., Inc.*, 80 F.3d 842, 853 (3d Cir. 1996)); *cf. Rockford*, 360 F. Supp. 3d at 752 (dismissing co-plaintiff Acument’s antitrust

claims under indirect purchaser rule because “plaintiffs allege that Acument paid CVS for Acthar and not [Express Scripts]”).

D. Plaintiff Has Not Plausibly Alleged Conspiracy

A claim for conspiracy under Section 1962(d) similarly requires plausible allegations of racketeering activity or conspiracy to commit racketeering activity. *See* 18 U.S.C. § 1962(d). For the same reasons Plaintiff has not sufficiently alleged a RICO enterprise, Plaintiff has also failed to allege a RICO conspiracy. To state such a claim, Plaintiff must allege that “(1) the defendant agreed to maintain an interest in or control of an enterprise . . . through a pattern of racketeering activity, and (2) the defendant further agreed that someone would commit at least two predicate acts to accomplish those goals.” *United Food*, 719 F.3d at 856. “Just as the complaint fails to allege that [UBC] acted on behalf of [the alleged] enterprise, it equally fails to allege that [UBC] *agreed* to act on behalf of the enterprise.” *See id.*

II. THE PENNSYLVANIA UTPCPL AND NEGLIGENT MISREPRESENTATION CLAIMS (COUNTS III-V) SHOULD BE DISMISSED

To state a deceptive conduct claim under the UTPCPL, a plaintiff must allege (1) a deceptive act; (2) justifiable reliance on the deceptive conduct; and (3) a resulting ascertainable loss. *See Yandrisovitz v. Ohio State Life Ins. Co.*, 2018 WL 4203840, at *5 n.7 (E.D. Pa. Aug. 31, 2018). Similarly, to plead a claim for negligent misrepresentation, Plaintiff must allege (1) a material misrepresentation that Defendant should have known was false; (2) upon which Defendant intended Plaintiff to rely; and (3) which injured Plaintiff due to its justifiable reliance. *See Bortz v. Noon*, 729 A.2d 555, 561 (Pa. 1999). The same deficiencies that doom Plaintiff’s RICO claims also require dismissal of Plaintiff’s UTPCPL and negligent misrepresentation claims.

First, as discussed above, Plaintiff has not alleged that UBC made any false statement.

As the basis for its UTPCPL claim, Plaintiff instead relies on allegations that do not involve deception, concededly do not apply to UBC, or which are only implausibly attributed to UBC. For instance, Plaintiff alleges that UBC “enter[ed] into the exclusive distribution arrangement” without “disclosing the same to Local 420” (Compl. ¶ 521(a)), but admits that distribution agreement (which was between Mallinckrodt and CuraScript, not UBC (*id.* ¶ 8)) was publicly announced (*id.* ¶ 521(c)). Plaintiff alleges that this announcement was still deceptive because it “failed to disclose that [Acthar prescriptions] were now being coordinated through UBC” (*id.* ¶ 521(c)), but that fact was clearly stated on the Acthar Start Form that was “put in place in 2007” (*id.* ¶ 96), and “which every patient and health care provider . . . is required to fill out and sign prior to receiving Acthar.” (*id.* ¶ 38; *see also id.*, Ex. A, at 1 (identifying UBC as “the current operator of the Acthar Hub”)).

Plaintiff also alleges that UBC “conspired and agreed to adopt the above-described ASAP program and the Acthar Start Form . . . in order to mislead and deceive” Plaintiff (*id.* ¶521(b)). But conclusory allegations that UBC was or should have been aware of any purported deceptive purpose are implausible because the *facts* that are pled suggest only that UBC was operating its legitimate business, not participating in any conspiracy, *see supra*, at 9–11. Further, and tellingly, Plaintiff, who purchased Acthar in 2018 (Compl. ¶265), acknowledges that in May 2017, the *previous* year, UBC’s then corporate parent publicly stated that Acthar “is vastly overpriced for its value.” (*Id.* ¶ 221.) There is thus similarly no plausibility to Plaintiff’s conclusory allegation that “UBC misled and deceived [Plaintiff] in the decision to raise the prices of Acthar, and the lack of value of Acthar for the prices being charged.” (*Id.* ¶ 521(d)); *see also id.* ¶ 212 (Mallinckrodt alone “could, and did directly, control and raise the AWP for Acthar”).)

Second, Plaintiff also has not alleged that it justifiably relied on any misrepresentation from UBC. *See Yandrisovitz*, 2018 WL 4203840, at *5 (citing *Hunt v. U.S. Tobacco Co.*, 538 F.3d 217, 224 (3d Cir. 2008)) (UTPCPL claim requires “Plaintiffs to allege justifiable reliance on a misrepresentation made by Defendants”); *see also Tran v. Metro. Life Ins. Co.*, 408 F.3d 130, 140 (3d Cir. 2005) (to succeed on UTPCPL claim, “plaintiffs must demonstrate the level of reliance that accompanies a common law fraud claim” (quoting *Toy v. Metro. Life Ins. Co.*, 863 A.2d 1, 11 (Pa. Super. Ct. 2004))). Plaintiff conclusorily asserts that it was “injured as a result of the Defendants’ conduct . . . by virtue of having paid for Acthar” at allegedly “inflated prices” (Compl. ¶ 523), but has failed to identify any choice it would have made differently were it not for the allegedly deceptive acts, or why such allegations would be plausible given what Plaintiff describes as a “captive market” (*id.* ¶ 153) for Acthar. *See Hunt*, 538 F.3d at 227 (plaintiff did not allege justifiable reliance when he did not allege that the defendant’s deception induced him to purchase its products or engage in any other detrimental activity); *see also supra*, at 11–12 (explaining why Plaintiff failed to sufficiently allege causation).

III. THE CLASS CLAIMS BASED ON OTHER STATES’ CONSUMER PROTECTION LAWS (COUNT IV) SHOULD BE DISMISSED

Plaintiff’s class claims must be dismissed against UBC because Plaintiff does not make *any* allegations against UBC to support them. The issue of whether class allegations are sufficient can be resolved on a motion to dismiss. *See Gen. Tel. Co. v. Falcon*, 457 U.S. 147, 160 (1982) (“[S]ometimes the issues are plain enough from the pleadings to determine whether the interests of the absent parties are fairly encompassed within the named plaintiff’s claim.”); *see also Hodczak v. Latrobe Specialty Steel Co.*, 2009 WL 911311 (W.D. Pa. Mar. 31, 2009) (granting summary judgment and denying discovery as to collective action claim plaintiffs failed to “ple[a]d any facts in the complaint to support a collective action claim”).

Here, the Complaint does not even assert, let alone plausibly allege, that the putative class members are similarly situated with respect to any conduct by UBC. Instead, Plaintiff asserts only that the putative class’s claims are sufficiently similar because each member “paid for Acthar at the inflated prices due to the unlawful conduct of **Mallinckrodt**.” (Compl. ¶ 449 (emphasis added).) Similarly, Plaintiff alleges the common factual and legal questions all relate to “**Mallinckrodt’s** misconduct” and that they predominate only because “**Mallinckrodt** has acted and refused to act on grounds generally applicable to the entire Class.” (*Id.* ¶¶ 452–53 (emphasis added).) The Complaint thus makes clear that Plaintiff’s class allegations cannot encompass any class claims against UBC.

Plaintiff’s factual allegations supporting his class claims under other state consumer protection laws⁴ further confirm that those claims must be dismissed against UBC. Plaintiff alleges only that “**Mallinckrodt** violated the consumer protection laws of all other states.” (*Id.* ¶ 528 (emphasis added).) Plaintiff does not even mention UBC’s name in any of the over 160 paragraphs Plaintiff devotes to these claims. (*See id.* ¶¶ 528–629; *see also, e.g., id.* ¶ 534 (alleging class members have “been injured as a direct and proximate result of **Mallinckrodt’s** unconscionable, unfair, and deceptive conduct” (emphasis added)); ¶ 576 (Plaintiff and the Class seek relief against **Mallinckrodt**” (emphasis added)).)

Because neither Plaintiff’s class allegations nor class claims include any allegations regarding UBC, those claims must be dismissed as to UBC. *Cf. Fleet Nat’l. Bank*, 2005 WL 2455673, at *11 (dismissing fraud claim against subset of individual defendants who were “not

⁴ Those claims are necessarily asserted solely on behalf of putative class members because third-party payors like Plaintiff have “standing to proceed only under the laws of the state in which that [payor] is based.” *In re Avandia Marketing, Sales Practices and Products Liability Litig.*, 2013 WL 5761202, at *9 (E.D. Pa. Oct. 23, 2013); *see also* Compl. ¶ 528 (“Plaintiff brings claims under the laws of these states on behalf of the consumer purchasers of Acthar in such states.”).

alleged to have made any misrepresentations” themselves).

IV. THE AIDING AND ABETTING AND CONSPIRACY CLAIM (COUNT VI) SHOULD BE DISMISSED

Plaintiff has failed to adequately plead a claim for aiding and abetting fraud or conspiracy to commit fraud. The former claim does not exist under Pennsylvania law. As to the latter, Plaintiff has failed to plead UBC acted with the requisite malice. Further, both claims would fail for the independent reason that Plaintiff has not sufficiently alleged any underlying fraud.

A. Pennsylvania Law Does Not Recognize a Claim for Aiding and Abetting Fraud

The Pennsylvania Supreme Court has not recognized a claim for aiding and abetting fraud. While authority is divided, this Court has previously held that it will “follow[] the lead of the majority of other courts in this district, in declining to expand Pennsylvania law, and hold[] that the Pennsylvania Supreme Court would not permit such an action.” *Id.* at *13. Plaintiff’s aiding and abetting claim therefore should be dismissed.

B. Plaintiff Does Not Sufficiently Allege UBC Aided and Abetted Any Fraud or Participated in Any Conspiracy

Even if Pennsylvania did recognize a claim for aiding and abetting fraud, Plaintiff has not pled it with adequate specificity against UBC. In particular, Plaintiff “makes no specific factual averments about what information [UBC] actually possessed” concerning any purported misrepresentation about Acthar. *See Fulton Fin. Advisors, Nat’l Ass’n v. NatCity Invs, Inc.*, 2013 WL 5635977, at *17 (E.D. Pa. Oct. 15, 2013). Nor does Plaintiff sufficiently allege any “specific actions [UBC] took, which would have substantially assisted or encouraged any fraudulent behavior” by other parties. *Id.*; *see also WM High Yield Fund v. O’Hanlon*, 2005 WL 6788446, at *14 (E.D. Pa. May 13, 2005) (claim for civil conspiracy requires, inter alia, an “overt act done in pursuance of the common purpose.”). Rather, as explained above, Plaintiff

only alleges that UBC provided services to Mallinckrodt as part of its ordinary, legitimate business operations. *See supra*, at 9–11.

C. Plaintiff Has Failed to Allege That UBC Acted with the Requisite Malice

Plaintiff has also failed to allege civil conspiracy because the Complaint does not allege that UBC acted with the requisite malice. To meet that standard, Plaintiff must allege that “the *sole* purpose of the conspiracy is to cause harm to the party who has been injured.” *WM High Yield Fund*, 2005 WL 678844, at *14 (emphasis added) (collecting cases). The “Supreme Court of Pennsylvania [has] held that where the facts show that a person acted to advance his own business interests, those facts constituted justification and negated any alleged intent to injure.” *Id.* at *15 (discussing *Thompson Coal Co. v. Pike Coal Co.*, 412 A.2d 466, 472 (Pa. 1979)). In *WM High Yield Fund*, this Court rejected a conspiracy claim because the purpose of the asserted conspiracy was to “enable [the defendant] to raise new capital to fund its growth.” *Id.* Here, the purpose of any of UBC’s actions was to operate its legitimate business providing administrative support and other services to connect pharmaceutical manufacturers, payors, and patients. *See supra*, at 9–11. Plaintiff has therefore failed to plead a claim for civil conspiracy against UBC.

D. Plaintiff Has Failed to Sufficiently Allege Any Underlying Fraud

Further, as explained above, Plaintiff has failed to sufficiently allege any fraud that UBC aided and abetted or entered into any conspiracy to pursue. *See supra*, at 6–9. The aiding and abetting and conspiracy claim should be dismissed for that independent reason as well.

V. THE UNJUST ENRICHMENT CLAIM (COUNT VII) SHOULD BE DISMISSED

Plaintiffs’ unjust enrichment claims also fail as a matter of law. To state such a claim under Pennsylvania law, Plaintiffs must allege (1) a benefit conferred on one party by another; (2) appreciation of the benefit by the recipient; and (3) acceptance and retention of the benefit under circumstances that would make it inequitable for the recipient to retain the benefit without

providing compensation. *Osness v. Lasko Prods., Inc.*, 868 F. Supp. 2d 402, 414 (E.D. Pa. 2012). Here, Plaintiff cannot meet any of the three elements.

First, Plaintiff fails to satisfy either the first or second element because the Complaint does not allege that Plaintiff conferred any benefit on UBC, or that UBC received or “appreciated” any benefit from Plaintiff. The benefit alleged is payments for Acthar, but Plaintiff alleges that *Mallinckrodt* “receive[d] guaranteed payments **directly** from the TPPs” like Plaintiff. (Compl. ¶ 158 (emphasis added).) That Mallinckrodt also “compensated UBC” for its services (*id.* ¶ 725) is immaterial because the Complaint does not allege how UBC’s compensation **increased** as a result of any alleged overcharging. See *Telwell Inc. v. Grandbridge Real Estate Capital LLC*, 143 A.3d 421, 428 (Pa. Super. 2016) (affirming summary judgment on unjust enrichment claim in favor of defendant who “transmitted any overpayment” to a different defendant and therefore did not “receive[] any benefit, financial or otherwise from overcharging” the plaintiff).

Second, even if UBC had been enriched, Plaintiff does not plead any “facts to support an inference that the enrichment . . . was unjust.” *Osness*, 868 F. Supp. 2d at 415. Plaintiff’s unjust enrichment theory is predicated on its allegations that it was defrauded by UBC. But Plaintiff has not sufficiently pled any underlying fraud. That failure equally requires dismissal of Plaintiff’s dependent unjust enrichment claim. *Id.*

Finally, Plaintiff’s unjust enrichment claim is pled as a companion to Plaintiff’s other tort claims. In other words, that claim “rests on the same improper conduct” as Plaintiffs’ RICO, UTPCPL, and other state law claims. See *Whitaker v. Herr Foods, Inc.*, 198 F. Supp. 3d 476, 493 (E.D. Pa. 2016) (citing *Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc.*, 171 F.3d 912, 936 (3d Cir. 1999)). Such claims “rise or fall with the underlying [tort]

claim.” *Id.* Because each of Plaintiffs’ independent tort claims fail as a matter of law, *see supra*, at 5–16, Plaintiffs’ unjust enrichment claim must fail as well.

VI. THE CLAIM FOR DECLARATORY AND INJUNCTIVE RELIEF (COUNT VIII) SHOULD BE DISMISSED

Plaintiff’s equitable relief claims fail for the same reasons as the substantive claims, and further because Plaintiff can simply stop covering Acthar if it feels aggrieved by the price that Mallinckrodt charges. Plaintiff’s speculation that it may “have to pay for Acthar in the future” is insufficient to support a viable claim for declaratory or injunctive relief. (Compl. ¶ 731.) Claims for declaratory relief require a “case of actual controversy” and cannot seek “an opinion advising what the law would be upon a hypothetical state of facts.” *State Farm Mut. Auto. Ins. v. Lugiano*, 2015 WL 8482800, at *3 (E.D. Pa. Dec. 10, 2015) (citing *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240–41 (1937)). Similarly, a plaintiff lacks standing to seek injunctive relief unless it shows that “a ‘real or imminent threat’ of harm creates ‘a likelihood of substantial and immediate irreparable injury.’” *Landau v. Viridian Energy PA LLC*, 223 F. Supp. 3d 401, 420 (E.D. Pa. 2016). Plaintiff has failed to allege either an actual controversy or threat of harm to support a claim for declaratory or injunctive relief.

Further, even if Plaintiff did decide to cover and pay for Acthar in the future, that decision would be disconnected from its claims here. Plaintiff cannot allege that such a decision was in any way caused by a fraudulent scheme of which Plaintiff is now allegedly aware and asserts as the basis for this lawsuit. *Cf. McNair v. Synapse Grp., Inc.*, 672 F.3d 213, 225–26 (3d Cir. 2017) (dismissing claim for injunctive relief because whether plaintiffs would again “accept an offer” from the party that allegedly defrauded them was “a matter of pure speculation.”); *Landau*, 223 F. Supp. 3d at 421 (“The possibility that [plaintiff] might enter a new contract with [defendant] despite his prior unhappy experience does not establish a likelihood of future injury

sufficient to confer standing.”).

CONCLUSION

For the foregoing reasons, all claims against Defendant UBC should be dismissed with prejudice.

Dated: August 20, 2019

Respectfully submitted,

/s/ Joseph P. Walsh

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CERTIFICATE OF SERVICE

I hereby certify that on August 20, 2019, a true and correct copy of the foregoing document was electronically filed with the Clerk of Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ Joseph P. Walsh

PLAINTIFF'S EXHIBIT "C"

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

STEAMFITTERS LOCAL UNION NO. 420,

individually and on behalf of all others

similarly situated,

14420 Townsend Road

Philadelphia, PA 19154

Plaintiff,

v .

MALLINCKRODT ARD, LLC,

f/k/a Mallinckrodt ARD, Inc.;

f/k/a Questcor Pharmaceuticals, Inc.;

1425 U.S. Route 206

Bedminster, NJ 07921

UNITED BIOSOURCE CORPORATION,

now known as UNITED BIOSOURCE LLC,

a wholly owned subsidiary of UNITED

BIOSOURCE HOLDINGS, INC.

920 Harvest Drive

Blue Bell, PA 19422

Defendants.

Civil Action

File No. 2:19-cv-03047-BMS

**DEFENDANT MALLINCKRODT ARD LLC'S
MEMORANDUM OF LAW AND AUTHORITIES IN SUPPORT OF
ITS MOTION TO DISMISS STEAMFITTERS LOCAL UNION NO. 420'S COMPLAINT
PURSUANT TO RULE 12(b)(1) AND 12(b)(6)**

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Defendant Mallinckrodt ARD LLC (“Mallinckrodt”), by and through its undersigned counsel, hereby files this Memorandum of Law and Authorities in Support of its Motion to Dismiss with Prejudice the Complaint (“Complaint”) filed by Steamfitters Local Union No. 420 (“Plaintiff”). In support, Mallinckrodt states as follows:

INTRODUCTION

This lengthy, rambling Complaint about the price of Mallinckrodt’s H.P. Acthar Gel (“Acthar”) is a clumsy amalgamation of claims and allegations from several pending cases across the country brought by the same counsel on behalf of classes that overlap with the putative class here. Ultimately, Plaintiff’s grievance here—just as in the other cases filed by Plaintiff’s counsel—is that Mallinckrodt supposedly charged more for Acthar than Plaintiff now believes it is worth. The Complaint totals one hundred and sixty-six pages (741 paragraphs) and contains disparaging allegations about Mallinckrodt and others, but when distilled to its essence, it lacks the necessary allegations to plausibly state any cause of action against Mallinckrodt.

Plaintiff characterizes Mallinckrodt’s Acthar business as a combination of three supposedly unlawful schemes: (1) a routine vertical distribution arrangement established and publicly announced in 2007 (the so-called “Distribution Scheme”); (2) Mallinckrodt’s decision to charge more for Acthar over time (the so-called “Pricing Scheme”); and (3) Mallinckrodt’s engagement of physicians to research potential benefits of Acthar and educate health care providers about the drug (the so-called “Marketing Scheme”). Plaintiff claims that as a result of these “schemes,” in 2018, it paid an “inflated” price for Acthar that a physician prescribed to treat the rheumatoid arthritis of its employee’s spouse. Stripping out all the hyperbole and speculation, what remains describes the perfectly lawful business practices of a drug maker.

The claims made here are remarkably similar to those in previous cases filed by the same

Plaintiff's counsel— and such claims have been rejected by both this Court and the Third Circuit. First, in *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 250 (3d Cir. 2012), two plaintiff groups sought to recover against a pharmaceutical company under federal and New Jersey RICO laws. The plaintiffs claimed “that the defendants pursued illegal marketing campaigns to persuade physicians to prescribe certain drugs for off-label uses.” *Id.* at 239. But, “[t]he District Court found that both groups of plaintiffs lacked standing because, inter alia, they did not allege a plausible nexus between the assailed marketing campaign and the physicians’ decisions to prescribe certain drugs for off-label use.” *Id.* The Third Circuit affirmed the dismissal for lack of standing.

Similarly, in *Zafarana v. Pfizer, Inc.*, 724 F. Supp. 2d 545 (E.D. Pa. 2010), the plaintiffs brought claims under state common law and unfair trade, consumer fraud, and consumer protection statutes alleging that pharmaceutical companies had fraudulently marketed a dozen drugs for off-label uses and had used bribes and kickbacks. Plaintiffs alleged that this wrongdoing resulted in them being prescribed ineffective drugs with negative side effects and paying more than they would have for cheaper, better alternatives. The Court dismissed the entire amended complaint (without leave to amend) finding “that plaintiffs have not alleged, and likely cannot allege, a cognizable injury or sufficient theory of causation as would be required to sustain their claims.” 724 F. Supp. at 561.

Moreover, the Northern District of Illinois recently dismissed RICO, fraud, consumer protection, conspiracy, and unjust enrichment claims brought by Plaintiff's counsel against Mallinckrodt based on the same underlying conduct in *City of Rockford and Acument Global Technologies, Inc. v. Mallinckrodt ARD, Inc., et al.*, 360 F. Sup. 3d 730, 776-77 (N.D. Ill. 2019)

(the “Rockford Action”).¹ The claims here suffer the same fatal defects, and this case should be dismissed.

PLAINTIFF’S FACTUAL ALLEGATIONS

Plaintiff alleges Mallinckrodt acquired the rights to Acthar in 2001 through Questcor, Mallinckrodt’s predecessor, and that it continues to manufacture, market, and distribute Acthar to this day. Compl. ¶¶ 2, 3. Acthar is a “specialty pharmaceutical” distributed only through specialty pharmacy distributors” and “specialty pharmacy providers.” ¶ 4. Acthar is the only therapeutic ACTH product sold in the United States. ¶ 2. Plaintiff also alleges that in 2013 Questcor purchased the rights to develop, market, and sell a potentially competitive drug, Synacthen Depot (“Synacthen”), which supposedly allowed it to charge supra-competitive prices for Acthar. ¶¶ 197-199.

Starting in 2007, Mallinckrodt’s predecessor, Questcor, embarked on a “new strategy” which involved changes to the distribution, pricing, and marketing of Acthar. ¶ 6. Plaintiff alleges this strategy ultimately involved three “schemes” that allowed Defendants to raise the price of Acthar. ¶ 7. First, Plaintiff alleges Defendants created a “Distribution Scheme” by which Mallinckrodt “limited the distribution of Acthar from multiple distribution outlets to just one, CuraScript, and engaged UBC to act as its exclusive “HUB” of operations.” ¶ 8. Relatedly, Plaintiff alleges that Mallinckrodt and UBC together adopted the “Acthar Support & Access Program” or “ASAP” through which UBC “confirms the prescription” “confirms the patient’s insurance coverage or other source of payment” and then “arranges for Acthar to be delivered” to

¹ The *City of Rockford* case also involves the same Plaintiff’s lead counsel and brings claims based on the same factual allegations on behalf of a putative class of third-party payors for Acthar that overlaps with the putative class here. Accordingly, on August 20, 2019, Defendants filed a Motion to Transfer to have this case moved from the Eastern District of Pennsylvania to the Northern District of Illinois, where the *City of Rockford* case is currently pending.

the patient. ¶ 159-163. Second, Plaintiff alleges a “Pricing Scheme,” by which Mallinckrodt “willfully manipulated and inflated the prices paid by TPPs for Acthar.” ¶ 11. Third, Plaintiff alleges a “Marketing Scheme,” “designed to ensure that Acthar was reimbursed by TPPs at the new, inflated AWP, without substantial backlash from patients and payors.” ¶ 12.

Relatedly, Plaintiff contends that Acthar has “limited clinical data” and “lack of proven safety or efficacy” and that Mallinckrodt has “consistently misrepresented to the public the value of Acthar.” ¶¶ 244, 386, 389. Specifically, Plaintiff contends that Mallinckrodt used “key opinion leaders” to cultivate prescribers of Acthar by generating false clinical data about the drug and its off-label uses and disseminating such data to doctors. *See, e.g.*, ¶¶ 247, 250. Plaintiff further alleges “part of Mallinckrodt’s long term business strategy [is] to promote the administration of Acthar as a maintenance medication for all indications where it is approved only for the treatment of acute episodes or exacerbations of the disease.” ¶ 392. Specifically, Plaintiff claims “Mallinckrodt has falsely and misleadingly promoted the sale of Acthar for the long-term treatment of MS, NS, SLE and RA, despite its limited approval for only acute exacerbations.” ¶ 391. Through these “three schemes,” Plaintiff claims Defendants were able to artificially raise the price of Acthar. ¶ 7.

Plaintiff is a third party payor that provides healthcare benefits to its employees through an insurer, Independence Blue Cross, with the assistance of a pharmacy benefits manager, Future Scripts. ¶ 28. Plaintiff alleges that in 2018, it paid for four prescriptions of Acthar for the spouse of one of its members for the treatment of a rheumatic disorder. *Id.* ¶ 29. Plaintiff does not allege that it purchased Acthar directly from Mallinckrodt. Strangely, although the crux of the Complaint is that Acthar costs more than it is worth, Plaintiff has not yet “decide[d] about whether to cover” Acthar prescriptions for “the new indications” going forward. ¶ 735.

ARGUMENT

I. Overview of Federal Pleading Requirements

To survive a motion to dismiss under Rule 12(b)(6), “a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.” *Santiago v. Warminster Twp.*, 629 F.3d 121, 128 (3d Cir. 2010) (quoting *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009)). This requires more than “a formulaic recitation of the elements of a cause of action.” *Burtch v. Milberg Factors, Inc.*, 662 F.3d 212, 220 (3d Cir. 2011) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). A court can “eliminate from consideration” any allegations that “are no more than conclusions” because such allegations “are not entitled to the assumption of truth.” *Finkelman v. Nat’l Football League*, 877 F.3d 504, 511 (3d Cir. 2017). Nor must it consider “legal conclusions, unsupported conclusions, unwarranted inferences, unwarranted deductions, footless conclusions of law, or sweeping legal conclusions cast in the form of factual allegations.” *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 n. 8 (3d Cir. 1997) (quotations omitted). At its core, a complaint must show “more than a sheer possibility that a defendant has acted unlawfully” and cannot stop “short of the line between possibility and plausibility of entitlement to relief.” *Burtch*, 662 F.3d at 221 (quoting *Iqbal*, 129 S. Ct. at 1949).

At the same time, “[a] motion to dismiss for want of standing is . . . properly brought pursuant to Rule 12(b)(1), because standing is a jurisdictional matter.” *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 243 (3d Cir. 2012).

II. Plaintiff’s Complaint Fails to Properly Plead the Elements of Any of its Claims and Should be Dismissed in its Entirety with Prejudice as to Mallinckrodt.

A. Plaintiff Fails to State a Claim Under 18 U.S.C. § 1962(c) (Count I).

To successfully state a RICO claim under § 1962(c), “the plaintiff must allege (1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity.” *In re Ins.*

Brokerage Antitrust Litig., 618 F.3d 300, 362 (3d Cir. 2010). Plaintiff fails to sufficiently allege any of the elements required to state a claim under § 1962(c).

1. Plaintiff has not Sufficiently Alleged a RICO Enterprise.

A RICO enterprise can include “any union or group of individuals associated in fact although not a legal entity.” 18 U.S.C. § 1961(4). “[A]n association-in-fact cannot reasonably be assumed to satisfy the elements of an enterprise and the allegations of the complaint must therefore receive greater scrutiny.” *Freedom Med. Inc. v. Gillespie*, 634 F. Supp. 2d 490, 505 (E.D. Pa. 2007). “[S]imply identifying the allegedly associated components does not serve to put defendants on notice of the RICO claim.” *In re Ins. Brokerage*, 618 F.3d at 369.

To properly plead a RICO enterprise here, Plaintiff must allege “a shared ‘purpose, relationships among those associated with the enterprise, and longevity sufficient to permit these associates to pursue the enterprise’s purpose.’” *Id.* at 370 (quoting *Boyle v. United States*, 556 U.S. 938, 946 (2009)). “[U]nless a plaintiff must ‘allege something more than the fact that individuals were all engaged in the same type of illicit conduct during the same time period,’ — the RICO statute’s allowance for association-in-fact enterprises becomes an open gateway to the imposition of potentially massive costs on numerous defendants, regardless of whether there is even a hint of the collaboration necessary to trigger liability.” *In re Ins. Brokerage*, 618 F.3d at 369 (quoting *Elsevier Inc. v. W.H.P.R., Inc.*, 692 F. Supp. 2d 297, 307 (S.D.N.Y. 2010)).

Here, Plaintiff claims the alleged enterprise is “the Acthar Marketing Enterprise, an association in fact . . . consisting of i) Mallinckrodt, and its MSLs and sales representatives, (ii) UBC, and its RSs, and (iii) KOLs, both named and unnamed in this Complaint.” Compl. ¶ 485. Because the alleged enterprise is an “association-in-fact”(as opposed to a legal entity), Plaintiff must plausibly allege the structural features discussed in *Boyle* to avoid dismissal. It does not.

Plaintiff, for example, concludes that Defendants “associated together for the common purpose of promoting Acthar for off-label uses and doses and earning profits therefrom.” Compl. ¶ 486. But Plaintiff offers no facts plausibly showing Defendants actually shared this alleged purpose, or that such a purpose motivated the alleged enterprise. Because conclusory allegations “are not entitled to the assumption of truth,” Plaintiff has failed to show the alleged enterprise shared a common purpose. *Finkelman*, 877 F.3d at 511.

Nor can allegations of “run of the mill” business activities establish a RICO enterprise. *See Bolick v. Ne. Indus. Servs. Corp.*, 2015 WL 540066, at *12 (M.D. Pa. Feb. 10, 2015) (dismissing RICO claims where plaintiff did not allege defendants participated in alleged enterprise as opposed to simply providing run-of-the-mill commercial services in conducting their businesses); *MSP Recovery Claims, Series, LLC v. Sanofi Aventis U.S. LLC*, 2019 WL 1418129, at *13 (D.N.J. Mar. 29, 2019) (quoting *Bible v. United Student Aid Funds, Inc.*, 799 F.3d 633 (7th Cir. 2015)) (noting a “run-of-the-mill commercial relationship where each entity acts in its individual capacity to pursue its individual self-interest” cannot form the basis of a RICO enterprise). Here, after setting aside conclusory allegations, the Complaint describes nothing more than a run-of-the mill pharmaceutical drug marketing and distribution program.

In addition, Plaintiff fails to sufficiently allege “relationships among those associated with the enterprise.” *Boyle*, 556 U.S. at 946. Outside of broad assertions that Defendants collectively “controlled,” “conducted and participated” in the alleged enterprise, Plaintiff offers no allegations as to the alleged enterprise’s structure, decision making scheme, or management. This failure is fatal to Plaintiff’s RICO claim. *See In re Am. Inv’rs Life Ins. Co. Annuity Mktg. & Sales Practices Litig.*, 2006 WL 1531152, at *8 (E.D. Pa. June 2, 2006) (dismissing RICO claims in part for failing to allege any organizational structure within the alleged enterprise).

2. Plaintiff Fails to Allege Mallinckrodt Conducted or Participated in the Alleged Enterprise’s Affairs through a Pattern of Racketeering Activity.

It is well-settled that, “mere association with an enterprise does not violate 18 U.S.C. § 1962(c).” *In re Ins. Brokerage*, 618 F.3d at 370. “[A] defendant must ‘conduct or participate, directly or indirectly, in the conduct of such enterprise’s affairs through a pattern of racketeering activity.’” *Id.* at 370-71 (quoting 18 U.S.C. § 1962(c)). Plaintiff’s allegations fall short here as well.

A claim of mail or wire fraud requires: “(1) the defendant’s knowing and willful participation in a scheme or artifice to defraud, (2) with the specific intent to defraud, and (3) the use of the mails or interstate wire communications in furtherance of the scheme.” *United States v. Hedaithy*, 392 F.3d 580, 590 (3d Cir. 2004). Because the heightened pleading standard of Federal Rule of Civil Procedure 9(b) applies, such claims must “apprise defendants of the precise misconduct with which they are charged to protect them from spurious charges of fraudulent behavior.” *Freedom Med. Inc.*, 634 F. Supp. 2d at 509. Thus, courts have cautioned that “RICO claims premised on mail or wire fraud must be particularly scrutinized because of the relative ease with which a plaintiff may mold a RICO pattern from allegations that, upon closer scrutiny, do not support it.” *Kolar v. Preferred Real Estate Investments, Inc.*, 361 F. App’x 354, 363 (3d Cir. 2010) (quoting *Western Assocs. Ltd. P’ship v. Market Square Assocs.*, 235 F.3d 629, 637 (D.C. Cir. 2001)).

Here, Plaintiff does not allege any fraudulent behavior by Mallinckrodt, let alone with the requisite specificity. Plaintiff labels Mallinckrodt’s Acthar business practices as “schemes,” yet utterly fails to provide specific allegations of fraudulent behavior. Plaintiff appears to rest its RICO claims on alleged “misrepresentations” by Mallinckrodt. But the Complaint identifies no specific misrepresentations by Mallinckrodt sent by mail or wire. Plaintiff claims “both

Mallinckrodt and UBC misrepresent and deceive providers, patients and TPPs into prescribing, taking and paying for Acthar, respectively, for unapproved uses and doses” and that “Mallinckrodt has repeatedly and consistently misrepresented to the public the ‘value’ of Acthar for specific indications, including the rheumatoid disorder for which the Local 420 beneficiary was prescribed Acthar.” Compl. ¶ 389. But, Plaintiff fails to identify any specific public communications that are inaccurate.

Plaintiff contends Defendants committed “hundreds, if not thousands, of separate instances” of mail and wire fraud. Compl. ¶ 493. Yet Plaintiff fails to allege any facts showing a *single* instance of mail or wire fraud, much less with the specificity required by Rule 9(b). Plaintiff’s generalized allegation that Defendants used interstate mail and wires to participate in the enterprise are insufficient to defeat Mallinckrodt’s motion to dismiss. Here, like in *Rockford*, the Complaint “does not clarify what specifically was done over the internet and through the mail.” *Rockford*, 360 F. Supp. 3d 730, 744. Such generalized allegations do not support a cognizable RICO claim.

3. Plaintiff Lacks Standing and Fails to Allege RICO Injury or Causation.

Plaintiff alleges “overpayments for Acthar,” but bare allegations that a plaintiff “paid too much” for a product do not confer RICO standing. *See Maio v. Aetna, Inc.*, 221 F.3d 472, 501 (3d Cir. 2000) (dismissing RICO claims where plaintiffs asserted they “paid too much” for health insurance but did “not allege, for example, that they suffered medical injuries, received inadequate or inferior care, or sought but were denied necessary care as a consequence of the structure of [the insurance]”). Plaintiff does not, and cannot, offer allegations regarding the effectiveness of the drug or that it caused any medical injuries to Plaintiff’s beneficiaries. Plaintiff merely complains it paid too much for the drug which was prescribed for one of its employee’s spouses. This is insufficient to confer RICO standing.

Even if subjective grievances about paying too much for a drug alone gave rise to standing or could otherwise sustain a RICO claim, Plaintiff identifies no injury *caused* by Mallinckrodt's alleged RICO violations. A RICO violation must be both the "but for" and proximate cause of injury. *Holmes v. Sec. Investor. Prot. Corp.*, 503 U.S. 258, 268 (1992). Here, Plaintiff fails to plausibly allege that any action or misrepresentation by Mallinckrodt caused Plaintiff to decide to pay for Acthar. There is no nexus between the alleged harm and the alleged conduct to satisfy either type of causation.

As referenced above, *In re Schering Plough* is highly instructive on this point. *See* 678 F.3d 235, 250. There, plaintiffs argued "an overwhelming and reprehensible pattern of deceit by the defendants," including false marketing and illegal inducements to doctors, and that this scheme was aimed at the [third party payors]." *Id.* at 247. Additionally, plaintiffs made allegations that "prescriptions were written for off-label uses by physicians improperly influenced by the false and misleading statements, bribes, and other dishonest inducements brought to bear by Defendants' illegal off-label marketing scheme." *Id.* at 248. But, the Third Circuit affirmed the dismissal of federal and state RICO claims, among others, due to a lack of standing. In other words, there was no causal connection between the alleged injury (payments for the drug at issue) and the drug manufacturer's alleged wrongful marketing conduct.

Plaintiff in this case similarly seeks to recover based on fraudulent marketing of Acthar for off-label uses and an alleged illegal kickback scheme. But, like the plaintiffs in *In re Schering Plough*, Plaintiff lacks standing. Plaintiff's own allegations reveal the contingent steps that must occur before it reimburses for Acthar, which interrupt causation. The ASAP program requires "every patient and health care provider to fill out and sign" the Acthar start form "prior to receiving Acthar." Compl. ¶ 38. A physician must determine Acthar is "medically necessary"

before Mallinckrodt will ship Acthar to the patient. ¶ 165. “Once the patient (or their physician) seeks a prescription for Acthar . . . [t]hey are then required to fill out and fax back to UBC the Acthar Start Form in order to obtain Acthar.” ¶ 162. “[T]he patient authorizes Mallinckrodt and UBC, its ‘Designated operator’, to provide certain services to [the patient], including reimbursement and coverage support.” ¶ 167. UBC “confirms the patient’s insurance coverage or other source of payment . . . [and] then arranges for the Acthar to be delivered directly to the patient by CuraScript.” ¶ 163. “[T]he patient directly authorizes UBC, as Mallinckrodt’s agent, to ship Acthar directly to them, and to receive payment from both the patient (for the co-pay) and the TPP prior to obtaining the medication.” ¶ 167. Plaintiff does not describe the remaining steps, but common sense dictates they at least include the insurer here (Independence Blue Cross) and PBM (Future Scripts) approving the use of Acthar and the proposed payment.² And, of course, the patient must decide to proceed with the Acthar treatment. Such a theory of liability is far too remote to support a RICO claim.³

B. Plaintiff’s 18 U.S.C. § 1962(d) Claim (Count II) Similarly Fails.

“[A] § 1962(d) claim must be dismissed if the complaint does not adequately allege “an endeavor which, if completed, would satisfy all of the elements of a substantive [RICO] offense.” *In re Ins. Brokerage*, 618 F.3d at 373 (quoting *Salinas v. United States*, 522 U.S. 52, 65 (1997)). *See also Freedom Med. Inc.*, 634 F. Supp. 2d at 515 (“A section 1962(d) claim cannot be pursued where there is no cognizable RICO enterprise or pattern of racketeering activity alleged by the defendant or co-conspirators.”). Because Plaintiff’s substantive claim based on §

² In fact, the Complaint makes specific mention of another insurer, Aetna, refusing to approve payments for Acthar for certain indications. Compl. ¶187.

³ Furthermore, because Plaintiff did not purchase Acthar directly from Mallinckrodt, it was an “indirect” purchaser of the drug. *See In re Insulin Pricing Litig.*, 2019 WL 643709, at *11 (D.N.J. Feb. 15, 2019) (unpublished) (“[C]ourts may apply the indirect purchaser rule to RICO actions with the same force as under antitrust law”). Accordingly, its status as an indirect purchaser bars recovery for overpayments under RICO.

1962(c) is deficient, its conspiracy claim under § 1962(d) fails as well.

C. Plaintiff Fails to State a Claim Under Pennsylvania’s Unfair Trade Practices and Consumer Protection Law (“UTPCPL”) (Count III).

Plaintiff fails to allege a violation of UTPCPL. A viable UTPCPL claim requires: (1) a deceptive act that is likely to deceive a reasonable consumer; (2) justifiable reliance; and (3) that the plaintiff’s justifiable reliance caused ascertainable loss. *Seldon v. Home Loan Servs.*, 647 F.Supp.2d 451, 470 (E.D. Pa. 2009). Here, Plaintiff fails to satisfy each element of a UTPCPL claim.

The UTPCPL enumerates specific conduct that constitutes a violation, including, most expansively, “fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding.” 73. Pa. Stat. Ann. § 201 *et seq.* Plaintiff bases its UTPCPL claim on this provision, but does not allege an actionable or deceptive practice or misrepresentation in connection with its purchases of Acthar; instead, Plaintiff only lists supposed misrepresentations. Compl. ¶ 521. And, this Court has rejected vaguely pled UTPCPL claims. *Seldon*, 647 F. Supp. 2d at 470 (without alleging the “terms, conditions, or characteristics,” of allegedly deceptive conduct, “merely alleg[ing] a list of misrepresentations” is not enough).

Nor can alleged antitrust violations and anticompetitive conduct be a basis for a UTPCPL claim. *See Yeager’s Fuel, Inc. v. Penn. Power & Light Co.*, 953 F. Supp. 617 (E.D. Pa. 1997). Here, while Plaintiff attempts to renounce any antitrust claims, certain allegations in the Complaint are nearly identical to the allegations in the Rockford Action where *only* antitrust claims remain. In this scenario, Plaintiff’s characterizations of its claims are “distinction[s] without a difference.” *Panitch v. Quaker Oats Co.*, 2017 WL 1333285, at *4 (E.D. Pa. Apr. 5, 2017). Plaintiff’s claims revolve around the theory that Defendant’s “raise[d] and fix[ed] the prices of Acthar at supra-competitive levels.” Compl. ¶ 525. No matter how Plaintiff tries to

spin this, these are antitrust allegations, which are not among the enumerated violations of the UTPCPL.

Finally, to state a plausible claim under the UTPCPL, a plaintiff must also allege that it justifiably relied on the deceptive conduct. *Hunt v. U.S. Tobacco Co.*, 538 F.3d 217, 224 (3d Cir. 2008). “In other words, the Complaint must allege that knowledge of the deceptive conduct ‘would have changed [plaintiff]’s conduct.’” *Wilson v. Bank of Am., N.A.*, 48 F. Supp. 3d 787, 807 (E.D. Pa. 2014) (quoting *Hunt*, 538 F. 3d at 227); *see also Baker v. Family Credit Counseling Corp.*, 440 F. Supp. 2d 392, 412 (E.D. Pa. 2006) (to state a claim under UTPCPL, a plaintiff must allege defendant made a material misrepresentation that he justifiably relied upon). Moreover, “the existence of the ‘learned intermediary’ doctrine in Pennsylvania makes it difficult, if not impossible, for plaintiffs to successfully bring a UTPCPL claim based on a prescription drug.” *Zafarana v. Pfizer, Inc.*, 724 F. Supp. 2d at 557. Accordingly, in *Zafarana*, this Court dismissed plaintiff’s UTPCPL claim based on alleged misrepresentations concerning off-label uses of drugs because they could not show reliance. *Id.* at 558.

Here, despite one hundred sixty plus pages of conclusory allegations, Plaintiff’s UTPCPL claim fails to even facially allege the required element of reliance or suggest its losses stemmed from its justifiable reliance. It is well settled in the Third Circuit that “failure to allege justifiable reliance renders [UTPCPL claims] inadequate.” *Hunt*, 538 F. 3d at 228. Plaintiff’s UTPCPL claim must be dismissed.⁴

⁴ Moreover, once the sole named Plaintiff’s claims are dismissed, so must be the consumer protection claims of the unnamed class members under the consumer protection laws of the various other states set out in the Complaint. *See Zafarana*, 724 F.Supp.2d at 561-2. Furthermore, to the extent that other consumer protection statutes require reliance, Plaintiff’s claims fail for the same reasons as its UTPCPL claim.

D. Plaintiff's State Law Consumer Protection Claims Fail and Should be Dismissed.

Plaintiff's state consumer protection claims, which are based on the same alleged conduct as Plaintiff's RICO claims and claims under Pennsylvania Consumer Protection law, similarly fail. As set out below, Plaintiff lacks standing and/or otherwise fails to state claims under those laws.

a. Plaintiff Lacks Standing to Bring State Consumer Protection Claims in light of *Associated General Contractors of California, Inc. v. California State Council of Carpenters*.

The concept of antitrust standing, which stems from *Associated General Contractors*, 459 U.S. 519, 535 n.31 (1983) (hereinafter, "AGC"), has been extended to consumer protection cases in various states. *See generally Supreme Auto Transp. LLC v. Arcelor Mittal*, 238 F. Supp. 3d 1032, 1038–39 (N.D. Ill. 2017), *aff'd sub nom. Supreme Auto Transp., LLC v. Arcelor Mittal USA, Inc.*, 902 F.3d 735 (7th Cir. 2018) (addressing consumer protection laws of Alaska, Arkansas, California, Colorado, Delaware, the District of Columbia, Florida, Idaho, Maine, Massachusetts, Michigan, Montana, Nebraska, Nevada, New Hampshire, New York, North Carolina, Vermont, and Wisconsin). Other states incorporate an equivalent assessment of proximate causation.⁵

⁵ **Alabama:** *Billions v. White and Stafford Furniture Co., Inc.*, 528 So. 2d 878 (Ala. Civ. App. 1988) (the court held failure to allege damages occurred *as a result of* the act in violation of Alabama consumer protection was fatal to plaintiff's claim); **Arizona:** *Flagstaff Medical Center, Inc. v. Sullivan*, 773 F. Supp. 1325 (D. Ariz. 1991), *aff'd in part, rev'd in part on other grounds*, 962 F.2d 879 (9th Cir. 1992), as amended, (June 2, 1992) (applying Arizona law) (plaintiff must allege it relied on a misrepresentation and that the claimant's loss occurred as a result of an unlawful act or practice); **Minnesota:** *LeSage v. Norwest Bank Calhoun-Isles, N.A.*, 409 N.W.2d 536 (Minn. Ct. App. 1987) (plaintiffs seeking monetary damages under § 8.31 must show a legal nexus between the complained of acts and their alleged losses); **Oregon:** *Terry v. Holden-Dhein Enterprises, Ltd.*, 48 Or. App. 763, 618 P.2d 7 (1980) (plaintiff must establish loss occurred "as a result of" an unlawful practice); **Texas:** *City of Marshall, Tex. v. Bryant Air Conditioning Co.*, 650 F.2d 724, 31 U.C.C. Rep. Serv. 1329 (5th Cir. 1981) (applying Texas law) (plaintiff can only recover for damages actually caused by the deceptive trade practice); **Washington:** *Washington*

Under an AGC analysis, courts apply six AGC factors when evaluating whether a plaintiff is the “proper party” to bring suit, including: (1) directness of the injury; (2) risk of duplicate recovery or complex damage apportionment; (3) type of injury and whether it was one Congress sought to redress; (4) causal connection between the violation and the harm; (5) speculative nature of the damages; and (6) presence of improper motive. *Loeb Industries, Inc. v. Sumitomo Corp.*, 306 F. 3d 469, 484 (7th Cir. 2002); *see Allegheny Gen. Hosp. v. Philip Morris, Inc.*, 228 F.3d 429, 438 (3d Cir. 2000). “No single factor is decisive” and a court must “balance all of the factors” to determine whether standing is appropriate. *Serfecz v. Jewel Food Stores*, No. 82 C 4171, 1994 U.S. Dist. LEXIS 12239, at *6–7 (N.D. Ill. Aug. 31, 1994) (citing *R.C. Dick Geothermal v. Thermogenics*, 890 F.2d 139, 146 (9th Cir. 1989)).

Judge Kapala made clear in his earlier ruling in *City of Rockford v. Mallinckrodt*, 360 F. Supp. 3d 730, 752 (N.D. Ill. 2019) that a plaintiff lacks antitrust standing if it alleges that it paid an unrelated (non-Defendant) entity for Acthar. There, the Court held that a plaintiff lacked antitrust standing to sue where it alleged that it paid CVS for Acthar and not Express Scripts’s specialty pharmacy. Such allegations constituted “an additional wrinkle concerning the ‘directness’” inquiry of AGC. *Id.* at 752. In other words, the injury was too remote under AGC. The *Rockford* court further stated that such a plaintiff would “not meet even the least stringent state’s ‘proximate cause’ test.” *Id.* at 760.

State Physicians Ins. Exchange & Ass'n v. Fisons Corp., 122 Wash. 2d 299, 858 P.2d 1054, Prod. Liab. Rep. (CCH) ¶ 13675 (1993) (plaintiff must establish the claimant’s injury is causally linked to the unfair or deceptive act alleged); **Illinois:** *Connick v. Suzuki Motor Co.*, 174 Ill. 2d 482, 501, 675 N.E.2d 584, 593 (1996) (“valid [consumer protection] claim must show that the consumer fraud proximately caused plaintiff’s injury”); **Hawaii:** *Wiginton v. Pac. Credit Corp.*, 2 Haw. App. 435, 444, 634 P.2d 111, 118 (1981) (plaintiff must show that he was “wrongfully induced” by the statutory violation); **South Carolina:** *Charleston Lumber Co. v. Miller Hous. Corp.*, 318 S.C. 471, 482, 458 S.E.2d 431, 438 (Ct. App. 1995) (plaintiff must allege the alleged consumer protection violations proximately caused its injury).

Here, Plaintiff did not purchase Acthar directly from Mallinckrodt. Instead, Plaintiff alleges that its employees received healthcare benefits through Independence Blue Cross and received Acthar from Future Scripts, a pharmacy benefit manager *unrelated* to Defendant Express Scripts (or Mallinckrodt for that matter). *See* Compl. ¶ 28. This dooms Plaintiff’s state law consumer protection claims under any AGC or proximate cause analysis.

b. Other State Law Failings

Connecticut, Missouri, Ohio, Kentucky, Massachusetts. These states do not allow indirect purchasers, like Plaintiff, to bring consumer protection claims. *See In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 764 (E.D. Pa. 2014) (“[I]ndirect purchasers cannot seek recovery under either the Connecticut Antitrust Act or the Connecticut Unfair Trade Practices Act.”); *United Food & Comm. Workers Local 1776*, 74 F. Supp. 3d at 1086 (“indirect purchaser claim is barred under § 11” of the Massachusetts Consumer Protection Act); *Ireland v. Microsoft Corp.*, 2001 WL 1868946, at *1 (Mo.Cir. Jan. 24, 2001) (dismissing claims under Missouri’s antitrust law and consumer protection statute due to *Illinois Brick*); *Skilcraft Sheetmetal, Inc. v. Ky. Mack, Inc.*, 836 S.W.2d 907, 909 (Ky. Ct. App. 1992) (affirming dismissal of indirect purchasers’ claim under the Kentucky Consumer Protection Act because “a subsequent purchaser may not maintain an action against a seller with whom he did not deal”); *In re New Motor Vehicles Canadian Exp. Antitrust Litig.*, 350 F. Supp. 2d 160, 200 (D. Me. 2004)(“plaintiffs, as indirect purchasers, cannot assert a consumer protection claim for damages based upon anticompetitive conduct”).

Nevada, Idaho, and Nebraska. These states require intrastate activity to fall within the purview of their respective statutes. Nevada’s Unfair Trade Practice Act makes it unlawful to conduct enumerated activities “in this State.” Nev. Rev. Stat. § 598A.060. Likewise, the statute in Idaho limits application to conduct occurring within the state or impacting those within the

state. *See* Idaho Code Ann. § 48-602 (limiting relevant trade and commerce “either to or from locations within the state of Idaho, or directly or indirectly affecting the people of this state”). And, Nebraska’s Consumer Protection Act, Neb. Rev. Stat. §§ 59-1601, *et seq.*, “preclude[s] claims where the alleged injury is too remote.” *Kanne v. VISA USA Inc.*, 723 N.W.2d 293, 494-500 (2006). Plaintiff does not include allegations of improper conduct in these states which would violate the relevant statutes.

Georgia and Maine. Although both states permit private rights of action, the remedy is limited to injunctive relief. O.C.G.A. §10-1-373; Me. Rev. Stat. tit. 10, §1213; *see also Collins v. Athens Orthopedic Clinic*, 347 Ga. App. 13, 20-21 (2018) (explaining that the UDTPA only offers injunctive relief). Plaintiff’s claims for damages under these statutes should be dismissed.

West Virginia. “[T]he Supreme Court of West Virginia held ‘that the private cause of action afforded consumers under West Virginia Code § 46A-6-106(a) does not extend to prescription drug purchases.’” *In re Generic Pharm. Pricing Antitrust Litig.*, 368 F. Supp. 3d 814, 849 (E.D. Pa. 2019) (quoting *White v. Wyeth*, 227 W. Va. 131 (2010)). Thus, Plaintiff cannot recover under that statute here.

Alaska, Georgia, Louisiana and Montana. These states’ consumer protection statutes prohibit class actions. *In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 84 (D.Mass. 2005) (excluding consumers from Alaska, Georgia and Montana from class); *O’Quin v. Verizon Wireless*, 256 F.Supp.2d 512, 519 (M.D. La. 2003) (recognizing Louisiana’s ban on class actions). Plaintiff cannot proceed on behalf of a class for the consumer protection claims under these states’ laws.

Minnesota and Virginia. Minnesota and Virginia require allegations of fraudulent or deceptive conduct and mere allegations of anticompetitive conduct, like those in the Complaint,

will not satisfy this requirement. *See* Minn.Stat. § 325F.69(1); Va.Code Ann. §§ 59.1–196 to – 207.

Massachusetts, North Carolina, and New Hampshire. Massachusetts and North Carolina require consumer protection claims arise from primarily intrastate conduct. *See Fishman Transducers, Inc. v. Paul*, 684 F.3d 187, 197 (1st Cir. 2012) (dismissing consumer protection claims when the wrongdoing had “relevant and substantial impact across the county” and was not focused in Massachusetts); *In re Refrigerant Compressors Antitrust Litig.*, 2013 WL 1431756, at *19 (E.D. Mich. Apr. 9, 2013) (dismissing NC consumer protection claim because plaintiff did not allege any wrongful conduct in North Carolina); *Wilcox Indus. Corp. v. Hansen*, 870 F.Supp.2d 296 (D.N.H. 2012) (dismissing consumer protection claim where there was “simply no allegation that any offending conduct occurred in New Hampshire.”). Here, Plaintiff does not allege any wrongdoing that occurred in these state and therefore its claims must be dismissed. D.C.Code Ann. § 28–3904; Kan. Stat. Ann. § 50–626; N.M. Stat. Ann. § 57–12–2(D).

Florida. Claims under the Florida Deceptive and Unfair Trade Practices Act must be plead with particularity and courts have dismissed FDUTPA claims that allege, like here, a bare allegation that defendants “have engaged in unfair competition and unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201 *et seq.*” *In re Refrigerant Compressors Antitrust Litig.*, 2013 WL 1431756, at *21 (E.D. Mich. Apr. 9, 2013); *see* Compl. ¶ 592.

Kansas, Ohio, District of Columbia, and New Mexico. Kansas, Ohio, the District of Columbia, and New Mexico require pleading the alleged conduct is “unconscionable.” D.C. Code Ann. § 28–3904; Kan. Stat. Ann. § 50–626; N.M. Stat. Ann. § 57–12–2(D); *In re New Motor Vehicles*, 350 F. Supp. 2d at 198 (to state a claim under Ohio’s consumer protection law, plaintiff must allege “unconscionable conduct”). “Pleading unconscionability requires something

more than merely alleging that the price of a product was unfairly high.” *In re Graphics Processing Units Antitrust Litig.*, 527 F. Supp. 2d 1011, 1029 (N.D. Cal. 2007). Plaintiff claims Acthar is too expensive, and takes issue with marketing and distribution practices, but such allegations do not meet this unconscionability standard.

New York. To bring a claim under N.Y. Gen. Bus. Law § 349, the transaction through which a consumer is deceived must take place within New York. *See Goshen v. Mutual Life Ins. Co. of N.Y.*, 98 N.Y.2d 314, 746 N.Y.S.2d 858, 774 N.E.2d 1190, 1195 (2002). Here, there are no allegations of misconduct by Mallinckrodt in New York.

Florida, Maryland, and Minnesota. A heightened pleading standard applies to consumer protection claims under Florida and Minnesota law. *See* Minn. Stat. § 8.31, *et seq.*: *E-Shops Corp. v. U.S. Bank Nat’l Ass’n*, 795 F. Supp. 2d 874, 879 (D.Minn. 2011) (holding that Rule 9(b) applies to the Minnesota Consumer Fraud Act); *In re Packaged Ice Antitrust Litig.*, 779 F.Supp.2d 642, 665 (E.D.Mich. 2011) (dismissing FDUTPA claims by indirect purchasers for failure to plead fraud particularity under Rule 9(b)); *see Haley v. Corcoran*, 659 F. Supp. 2d 714 (D. Md. 2009) (Maryland Consumer Protection Claims are subject to a heightened pleading standard and also require plaintiff to allege reliance). Plaintiff has not pled its claims in a way that satisfies the heightened pleading standard.

North Dakota. Plaintiff alleges that “Mallinckrodt has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code 51-15-01, *et seq.*” Compl. ¶ 674. But, the state’s consumer protection statute “does not include the FTC Act’s prohibition on unfair acts or unfair competition but instead is limited to a proscription on deception, fraud and misrepresentation.” *In re New Motor Vehicles Canadian Exp. Antitrust Litig.*, 350 F. Supp. 2d 160, 197–199 (D. Me. 2004).

Virginia. Virginia requires that plaintiff allege it relied on a misrepresentation in order to state a claim under its consumer protection law. *Adams v. Children’s Hosp. of the King’s Daughters*, 100 Va. Cir. 68 (2018). Here, Plaintiff does not allege reliance and its claim should be dismissed.

Utah. Utah’s consumer protection statute requires “intrastate commerce in the state of Utah.” *See* Utah Code Ann. § 13-5-5. Here, Plaintiff does not allege *any* conduct that occurred in Utah and as a result, its claim should be dismissed.

South Dakota. South Dakota’s consumer protection law requires an “intentional misrepresentation or concealment of a fact on which plaintiff relied and that caused an injury to plaintiff.” *Nw. Pub. Serv., a Div. of Nw. Corp. v. Union Carbide Corp.*, 236 F. Supp. 2d 966, 973–74 (D.S.D. 2002) (applying South Dakota law). Here, Plaintiff has not alleged an intentional misrepresentation or concealment of fact nor has it alleged reliance or causation.

E. Plaintiff Fails to Sufficiently Plead a Claim for Negligent Misrepresentation (Count V).

This Court should dismiss Count V of Plaintiff’s Complaint as it fails to plead a claim for negligent misrepresentation. To state a claim for negligent misrepresentation under Pennsylvania law, a plaintiff is required to plead the following elements: “(1) a misrepresentation of material fact; (2) the representor must either know of the misrepresentation, must make the misrepresentation without knowledge of its falsity or must make the representation under circumstances in which he ought to know of its falsity; (3) the representor must intend the representation to induce another to act on it; and (4) injury must result to the party acting in justifiable reliance on the misrepresentation.” *Borough of Lansdowne, Pennsylvania v. Severson Env’tl. Servs., Inc.*, 2000 WL 1886578, at *5 (E.D. Pa. Dec. 12, 2000) (quoting *Williams Controls, Inc. v. Parente, Randolph, Orlando*, 39 F.Supp.2d 517 (M.D. Pa. 1999)).

Plaintiff has failed to satisfy its burden to state a claim for negligent misrepresentation under Pennsylvania law. Like with its other claims, Plaintiff's allegations surrounding its negligent misrepresentation claim are nothing more than conclusory allegations. For example, Plaintiff states "Mallinckrodt made multiple misrepresentations about the value of Acthar," but fails to point to any of these allegedly deceptive representations. Compl. ¶ 698. Moreover, "Pennsylvania law restricts liability for negligent misrepresentations to a 'person or limited group of persons'" for "whose benefit and guidance [defendants] intended to supply the information." *Wallace v. Sys. & Computer Tech. Corp.*, 1997 WL 602808, at *23 (E.D. Pa. Sept. 23, 1997). Plaintiff, a labor union, does not allege that any misrepresentation was directed to it by Mallinckrodt. Because Plaintiff's "misrepresentations" are nothing more than "a legal conclusion couched as a factual allegation," Plaintiff has not satisfied its burden and its negligent misrepresentation claim must be dismissed. *Dunstan v. Bayer Essure, Inc.*, 2017 WL 4392046, at *3 (E.D. Pa. Oct. 3, 2017). Moreover, as set out above, Plaintiff cannot show reliance.

F. Plaintiff Fails to State a Claim for Aiding and Abetting or Civil Conspiracy (Count VI) under Pennsylvania law.

This Court should dismiss Count VI of Plaintiff's Complaint because it does not state a claim under theories of aiding and abetting or civil conspiracy. First, with respect to aiding and abetting, "Pennsylvania has not adopted this cause of action." *S. Kane & Son Profit Sharing Tr. v. Marine Midland Bank*, 1996 WL 325894, at *9 (E.D. Pa. June 13, 1996). As a result, Plaintiff's aiding and abetting claim should be dismissed.

Next, to state a claim for conspiracy, Plaintiff must "plead and prove that two or more persons combined or agreed with intent to do an unlawful act or to do an otherwise lawful act by unlawful means." *Corrigan v. Methodist Hosp.*, 853 F. Supp. 832, 837 (E.D. Pa. 1994).

However, "Pennsylvania law mandates that 'absent a civil cause of action for a particular act,

there can be no cause of action for civil conspiracy to commit that act.” *Accurso v. Infra-Red Servs., Inc.*, 23 F. Supp. 3d 494, 512 (E.D. Pa. 2014) (quoting *Goldstein v. Phillip Morris, Inc.*, 854 A.2d 585, 590 (Pa.Super.Ct. 2004)).

Here, Plaintiff’s conspiracy claim rests on the same inadequate factual allegations underlying each of its previous substantive claims, none of which satisfy the requirements to state a claim under Pennsylvania law. Because a conspiracy claim cannot survive “without a viable underlying substantive claim,” Plaintiff’s conspiracy claim must be dismissed. *Id.*

G. Plaintiff Fails to Plead a Cognizable Claim for Unjust Enrichment (Count VII).

This Court should dismiss Count VII of Plaintiff’s Complaint because it fails to plead a claim for unjust enrichment. “In Pennsylvania, a party seeking to plead unjust enrichment must allege the following elements: (1) a benefit conferred on the defendant by the plaintiff; (2) appreciation of the benefit by the defendant; and (3) the defendant’s acceptance and retention of the benefit under such circumstances that it would be inequitable for defendant to retain the benefit without payment of value.” *Kliesh v. Select Portfolio Servicing, Inc.*, 2012 WL 2500973, at *8 (E.D. Pa. June 29, 2012). Moreover, “unjust enrichment claims are ‘not applicable to agreements deliberately entered into by the parties.’” *Montanez v. HSBC Mortg. Corp. (USA)*, 876 F. Supp. 2d 504, 515 (E.D. Pa. 2012) (quoting *Third Nat’l Bank & Trust Co. of Scranton v. Lehigh Valley Coal Co.*, 353 Pa. 185 (1945)). Here, Plaintiff cannot meet any of the three elements.

Plaintiff’s unjust enrichment claim rests on the same factual allegations as its faulty claims for consumer protection violations and negligent misrepresentations. In those claims, Plaintiff does nothing more than dress up legal conclusions as factual allegations, but such pleadings are not entitled to the presumption of truth. *Dunstan*, 2017 WL 4392046, at *3. In

other words, Plaintiff’s unjust enrichment claim “rests on the same improper conduct” as Plaintiff’s RICO, UTPCPL, and other state law claims. *See Whitaker v. Herr Foods, Inc.*, 198 F.Supp.3d 476, 493 (E.D. Pa. 2016) (citing *Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc.*, 171 F.3d 912, 936 (3d Cir. 1999)). Such claims “rise or fall with the underlying [tort] claim.” *Id.* Because each of Plaintiff’s other claims fail as a matter of law, its unjust enrichment claim must fail as well.

Moreover, Plaintiff fails to properly allege any benefit conferred on Mallinckrodt. Outside of the conclusory allegation that Mallinckrodt’s ASAP program was structured to ensure Mallinckrodt would receive “guaranteed payments directly from the TPPs who provide prescription drug coverage,” Plaintiff asserts no other facts suggesting Mallinckrodt received any benefit directly from Plaintiff. Compl. ¶ 158.

H. Plaintiff Fails to State a Claim for Declaratory & Injunctive Relief (Count VIII).

This Court should dismiss Count VIII of the Complaint because Plaintiff fails to state a claim for declaratory or injunctive relief. As a gateway matter, to have standing to pursue declaratory or injunctive relief, a plaintiff must establish a “case of actual controversy” or “a real or imminent threat of harm creates a likelihood of substantial and immediate irreparable injury.” *State Farm Mut. Auto. Ins. v. Lugiano*, 2015 U.S. Dist. LEXIS 165529, at *9 (E.D. Pa. Dec. 10, 2015); *Landau v. Viridian Energy PA LLC*, 223 F.Supp.3d 401, 420 (E.D. Pa. Nov. 30, 2016). Here, Plaintiff’s speculation that it may “have to pay for Acthar in the future” is insufficient to support a viable claim for declaratory or injunctive relief. Compl. ¶ 731.

Moreover, the Declaratory Judgment Act (“DJA”) authorizes a federal court “upon the filing of an appropriate pleading” to “declare the rights and other legal relations of any interested party seeking such a declaration.” 28 U.S.C. § 2201(a) (2010). The DJA does not provide a party

with an independent cause of action. Rather, the DJA is a procedural tool that allows courts to declare the substantive rights of the parties. *See Vaden v. Discover Bank*, 556 U.S. 49, 70 n.19 (2009) (DJA “does not enlarge the jurisdiction of the federal courts; it is ‘procedural only’”). Without an underlying substantive claim, a party cannot receive declaratory relief. *See Levy-Tatum v. Navient Sols., Inc.*, 183 F. Supp. 3d 701, 708 (E.D. Pa. 2016) (the DJA “presupposes the existence of a judicially remediable right”). Here, because declaratory judgment is a remedy and not a cause of action, Plaintiff’s claim fails. *Wagner v. Samsung Elecs. Am., Inc.*, 2016 WL 7209940, at *4 (E.D. Pa. Dec. 13, 2016) (holding declaratory judgment, like injunctive relief, is a remedy and not a separate cause of action). Moreover, even if Plaintiff properly pled a request for declaratory judgment, because its substantive claims fail as a matter of law, so too does its prayer for declaratory judgment. *Levy-Tatum*, 183 F. Supp. 3d at 708.⁶

I. In and of Itself, Plaintiff’s “Shotgun Pleading” Warrants Dismissal.

Federal Rule of Civil Procedure 8 requires “a short and plain statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. Pro. 8. “Complaints that violate this rule ‘are often disparagingly referred to as shotgun pleadings.’” *Bartol v. Barrowclough*, 251 F. Supp. 3d 855, 859 (E.D. Pa. 2017) (internal quotation omitted). The Third Circuit has been increasingly critical of “the all too common shotgun pleading approach to complaints,” and as a result, “shotgun pleadings” are often dismissed. *Id.* at 859 (E.D. Pa. 2017) (quoting *Hynson v. City of Chester Legal Dep’t*, 864 F.2d 1026, 1031 n.13 (3d Cir. 1988)). Plaintiff’s 160-plus page Complaint violates the mandate of a “short and plain statement” and falls squarely within the

⁶ Likewise, it is well settled in this Court that “[i]njunctive relief is a remedy and cannot be grounds for a separate claim.” *Wagner*, 2016 WL 7209940, at *4. “When a plaintiff includes both a separate count requesting the specific relief and again requests it in her concluding prayer for relief, the count should be dismissed.” Here, Plaintiff requests injunctive relief in both Count VII and in its final prayer for relief. As a result, Plaintiff’s claim for injunctive relief cannot survive.

Third Circuit’s interpretation of a shotgun pleading. The allegations set forth in the Complaint are vague and conclusory and do not provide “enough specific details as to each claim to put defendants on notice of what they are accused of doing.” *Grande v. Starbucks Corp.*, 2019 WL 1455445, at *3 (E.D. Pa. Apr. 2, 2019). At a minimum, Plaintiff should be required to re-plead.

CONCLUSION

For the reasons stated above, the Court should dismiss Plaintiff Steamfitters Local Union No. 420’s Complaint in its entirety with prejudice.

Dated: August 22, 2019

Respectfully Submitted,

/s/ Jonathan D. Weiss

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Attorneys for Defendant
Mallinckrodt ARD LLC

PLAINTIFF'S EXHIBIT "D"

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

STEAMFITTERS LOCAL

UNION NO. 420,

*Individually and on behalf of all others
similarly situated*

Plaintiffs,

v.

MALLINCKRODT ARD, LLC and
UNITED BIOSOURCE LLC,
Defendants.

CIVIL ACTION

No. 19-3047

ORDER

AND NOW, this 19th day of **December 2019**, upon consideration of Defendant United Biosource Corporation's Motion to Dismiss Complaint, Defendant Mallinckrodt's Ard LLC's Motion to Dismiss, Plaintiffs' responses, and all replies, it is **ORDERED** that:

1. United Biosource Corporation's motion (Document No. 18) is **DENIED**.¹
2. Mallinckrodt's motion (Document No. 26) is **DENIED**.

BY THE COURT:



Berle M. Schiller, J.

¹ Although this may be a situation in which the indirect purchaser rule applies to bar Plaintiffs' RICO claims, the Court cannot yet make that finding as a matter of law at this early stage of this litigation.

**CIRCUIT COURT OF SHELBY COUNTY, TENNESSEE
FOR THE THIRTIETH JUDICIAL CIRCUIT AT MEMPHIS**

ACUMENT GLOBAL TECHNOLOGIES, INC.,

Plaintiff,

v.

MALLINCKRODT ARD, INC., et al.,

Defendants.

Docket No. CT-2275-19

MOTION TO ADMIT J. KIRK GOZA TO PRACTICE *PRO HAC VICE*

Pursuant to Rule 19 of the Rules of the Tennessee Supreme Court, the undersigned, Nathan A. Bicks (“Movant” hereinafter), an attorney licensed and admitted to practice before this Court, moves for the entry of an order permitting the admission *pro hac vice* of J. Kirk Goza of the law firm Quinn, Emanuel, Urquhart & Sullivan, LLP, located at 1300 I Street NW, Suite 900, in Washington, D.C 20005.

Mr. Goza wishes to appear on behalf of Defendants Express Scripts Holding Company; Express Scripts, Inc.; CuraScript, Inc., doing business as CuraScript SD; Priority Healthcare Corp. and Priority Healthcare Distribution Inc., doing business as CuraScript SD; Accredo Health Group, Inc.; and United BioSource LLC (collectively the “Express Scripts Defendants”).

In support of this Motion, Movant would show to the Court:

1. As indicated by his affidavit attached hereto as Exhibit A, Mr. Goza is licensed to practice in the states of New York and California, and the District of Columbia, and is in good standing to practice in those jurisdictions.
2. Mr. Goza has not been suspended or made the subject of any disciplinary action in any court or bar.

3. Mr. Goza has never been sanctioned by the Board of Professional Responsibility of the Supreme Court of Tennessee, by any similar lawyer disciplinary agency in any jurisdiction, or by any similar lawyer disciplinary authority.

4. Mr. Goza consents to the disciplinary jurisdiction of the Board of Professional Responsibility of the Supreme Court of Tennessee and the courts of Tennessee in any matter arising out of his conduct in this proceeding, and further agrees to be bound by the Tennessee Rules of Professional Conduct and any other rules of conduct applicable to lawyers generally admitted in Tennessee.

5. Mr. Goza has paid all fees required by Tennessee Supreme Court Rule 19 in connection with this motion for admission.

6. Mr. Goza is a reputable and ethical attorney with the highest standards of personal conduct, and, as such, merits admission to practice *pro hac vice* before this Court.

WHEREFORE, Movant asks the Court to enter an order admitting Mr. Goza to practice *pro hac vice* in the above-captioned cause.

Respectfully submitted,



Nathan A. Bicks (#10903)

William D. Irvine, Jr. (#035193)

Lani D. Lester (#035226)

BURCH, PORTER & JOHNSON, PLLC

130 North Court Avenue

Memphis, TN 31803

Tel: (901) 524-5000

Facsimile: (901) 524-5024

Attorneys for the Express Scripts Defendants

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was sent by electronic mail or U.S. mail as required to all attorneys and all interested parties in this matter on this the 8 day of January, 2020.

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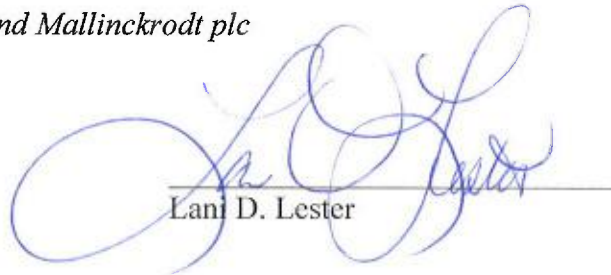
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Attorneys for Mallinckrodt ARC Inc. and Mallinckrodt plc



Lani D. Lester

**CIRCUIT COURT OF SHELBY COUNTY, TENNESSEE
FOR THE THIRTIETH JUDICIAL CIRCUIT AT MEMPHIS**

ACUMENT GLOBAL TECHNOLOGIES, INC.,

Plaintiff,

v.

MALLINCKRODT ARD, INC., et al.,

Defendants.

Docket No. CT-2275-19

CITY OF WASHINGTON

DISTRICT OF COLUMBIA

AFFIDAVIT OF J. KIRK GOZA

Before me, the undersigned, personally appeared J. Kirk Goza, who after being duly sworn makes oath and states as follows:

1. My full name is John Kirk Goza. My residence address 1421 Meridian Pl. NW, Washington, DC 20010. I am an attorney with Quinn Emanuel Urquhart & Sullivan, LLP, located at 1300 I St NW, Suite 900, Washington, D.C. 20005. My e-mail address is kirkgoza@quinnemanuel.com and my telephone number is 202-538-8169.

2. I seek to represent Defendants Express Scripts Holding Company; Express Scripts, Inc.; CuraScript, Inc., doing business as CuraScript SD; Priority Healthcare Corp. and Priority Healthcare Distribution Inc., doing business as CuraScript SD; Accredo Health Group, Inc.; and United BioSource LLC (collectively the "Express Scripts Defendants") in the above-captioned action.

3. I am licensed to practice law in the District of Columbia, admission date January 5, 2018, registration number 1531878; in the state of New York, admission date December 14, 2015,

registration number 5374343; and in the state of California, admission date June 4, 2014, registration number 297482.

4. I am in good standing in the District of Columbia, the state of New York, and the state of California. Certificates of Good Standing from the District of Columbia, the state of New York, and the state of California are attached as Exhibits A, B, and C to this Affidavit and incorporated herein.

5. I have not been previously admitted *pro hac vice* in any trial or appellate court of Tennessee.

6. I have never been denied admission *pro hac vice*, nor have I had an admission *pro hac vice* revoked by any court in any jurisdiction.

7. I have never been disciplined or sanctioned by the Board of Professional Responsibility of the Supreme Court of Tennessee, by any similar lawyer disciplinary agency in any jurisdiction, or by any similar lawyer disciplinary authority.

8. There are no disciplinary actions or investigations concerning my conduct as a lawyer pending before the Board of Professional Responsibility of the Supreme Court of Tennessee, before any similar lawyer disciplinary agency in any jurisdiction, or before any similar lawyer disciplinary authority.

9. I am familiar with the Tennessee Rules of Professional Conduct and the rules governing the proceedings of the Circuit Court of Shelby County, Tennessee.

10. I consent to the disciplinary jurisdiction of the Board of Professional Responsibility of the Supreme Court of Tennessee and the courts of Tennessee in any matter arising out of the my conduct as a lawyer in the above-captioned action. I agree to be bound by the Tennessee Rules

of Professional Conduct and any other rules of conduct applicable to lawyers generally admitted in Tennessee.

11. I am associated with Nathan Bicks (#10903), of the law firm Burch, Porter & Johnson, PLLC located at 130 North Court Avenue Memphis, TN 31803. Mr. Bicks's telephone number is (901) 524-5000.

12. I have paid all fees required by this Rule in connection with the Motion for Admission.

13. Service of the *pro hac vice* motion and all associated papers will be made upon all counsel of record in the proceeding and upon the Board of Professional Responsibility of the Supreme Court of Tennessee.

I declare under penalty of perjury that the foregoing is true and correct.



Pro Hac Vice Applicant

Sworn to and subscribed before me this 31 day of October, 2019





Notary Public

My commission expires: 8/31/20

EXHIBIT A



On behalf of JULIO A. CASTILLO, Clerk of the District of Columbia Court of Appeals,
the District of Columbia Bar does hereby certify that

John Kirk Goza

was duly qualified and admitted on January 5, 2018 as an attorney and counselor entitled to
practice before this Court; and is, on the date indicated below, an Active member in good
standing of this Bar.

**In Testimony Whereof,
I have hereunto subscribed my
name and affixed the seal of this
Court at the City of
Washington, D.C., on October
25, 2019.**

Julio A. Castillo

JULIO A. CASTILLO
Clerk of the Court

A handwritten signature in black ink, appearing to read "H. Goza".

Issued By:
District of Columbia Bar Membership

For questions or concerns, please contact the D.C. Bar Membership Office at 202-626-3475 or email
memberservices@dcbar.org.

EXHIBIT B

**Appellate Division of the Supreme Court
of the State of New York
First Judicial Department**

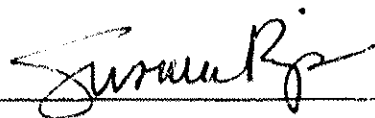
I, Susanna Rojas, Clerk of the Appellate Division of the Supreme Court of the State of New York, First Judicial Department, certify that

JOHN KIRK GOZA

was duly licensed and admitted to practice as an Attorney and Counsellor at Law in all the courts of the State of New York on December 14, 2015, has duly taken and subscribed the oath of office prescribed by law, has been enrolled in the Roll of Attorneys and Counsellors at Law on file in my office, has duly registered with the administrative office of the courts, and according to the records of this court is in good standing as an attorney and counsellor at law.

In Witness Whereof, I have hereunto set my
hand and affixed the seal of this court on

October 25, 2019



Clerk of the Court

EXHIBIT C



Supreme Court of California

JORGE E. NAVARRETE
Clerk and Executive Officer of the Supreme Court

CERTIFICATE OF THE CLERK OF THE SUPREME COURT OF THE STATE OF CALIFORNIA

JOHN KIRK GOZA

I, JORGE E. NAVARRETE, Clerk/Executive Officer of the Supreme Court of the State of California, do hereby certify that JOHN KIRK GOZA, #297482, was on the 4th day of June 2014, duly admitted to practice as an attorney and counselor at law in all the courts of this state, and is now listed on the Roll of Attorneys as a member of the bar of this state in good standing.

*Witness my hand and the seal of the court
on the 25th day of October 2019.*

JORGE E. NAVARRETE
Clerk/Executive Officer of the Supreme Court

By: 
C. Wong, Senior Deputy Clerk

**CIRCUIT COURT OF SHELBY COUNTY, TENNESSEE
FOR THE THIRTIETH JUDICIAL CIRCUIT AT MEMPHIS**

ACUMENT GLOBAL TECHNOLOGIES, INC.,

Plaintiff,

v.

MALLINCKRODT ARD, INC., et al.,

Defendants.

Docket No. CT-2275-19

MOTION TO ADMIT BRIAN H. ROWE TO PRACTICE *PRO HAC VICE*

Pursuant to Rule 19 of the Rules of the Tennessee Supreme Court, the undersigned, Nathan A. Bicks (“Movant” hereinafter), an attorney licensed and admitted to practice before this Court, moves for the entry of an order permitting the admission *pro hac vice* of Brian H. Rowe of the law firm Quinn, Emanuel, Urquhart & Sullivan, LLP, located at 1300 I Street NW, Suite 900, in Washington, D.C 20005.

Mr. Rowe wishes to appear on behalf of Defendants Express Scripts Holding Company; Express Scripts, Inc.; CuraScript, Inc., doing business as CuraScript SD; Priority Healthcare Corp. and Priority Healthcare Distribution Inc., doing business as CuraScript SD; Accredo Health Group, Inc.; and United BioSource LLC (collectively the “Express Scripts Defendants”).

In support of this Motion, Movant would show to the Court:

1. As indicated by his affidavit attached hereto as Exhibit A, Mr. Rowe is licensed to practice in the state of Illinois and the District of Columbia, and is in good standing to practice in both jurisdictions. Mr. Rowe has also been admitted to practice before the United States District Courts for the Northern District of Illinois, the District of Columbia, the Central District of Illinois, and the District of Colorado.

2. Mr. Rowe has not been suspended or made the subject of any disciplinary action in any court or bar.

3. Mr. Rowe has never been sanctioned by the Board of Professional Responsibility of the Supreme Court of Tennessee, by any similar lawyer disciplinary agency in any jurisdiction, or by any similar lawyer disciplinary authority.

4. Mr. Rowe consents to the disciplinary jurisdiction of the Board of Professional Responsibility of the Supreme Court of Tennessee and the courts of Tennessee in any matter arising out of his conduct in this proceeding, and further agrees to be bound by the Tennessee Rules of Professional Conduct and any other rules of conduct applicable to lawyers generally admitted in Tennessee.

5. Mr. Rowe has paid all fees required by Tennessee Supreme Court Rule 19 in connection with this motion for admission.

6. Mr. Rowe is a reputable and ethical attorney with the highest standards of personal conduct, and, as such, merits admission to practice *pro hac vice* before this Court.

WHEREFORE, Movant asks the Court to enter an order admitting Mr. Rowe to practice *pro hac vice* in the above-captioned cause.

Respectfully submitted,



Nathan A. Bicks (#10903)

William D. Irvine, Jr. (#035193)

Lani D. Lester (#035226)

BURCH, PORTER & JOHNSON, PLLC

130 North Court Avenue

Memphis, TN 31803

Tel: (901) 524-5000

Facsimile: (901) 524-5024

Attorneys for the Express Scripts Defendants

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was sent by electronic
mail or U.S. mail as required to all attorneys and all interested parties in this matter on this the
8th day of January, 2020.

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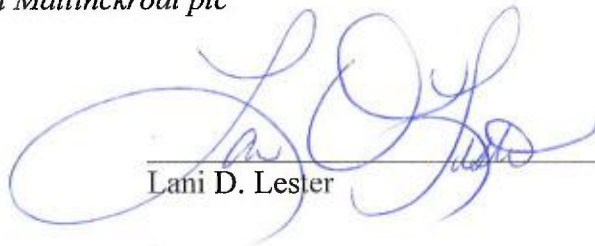
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Attorneys for Mallinckrodt ARC Inc. and Mallinckrodt plc



Lani D. Lester

**CIRCUIT COURT OF SHELBY COUNTY, TENNESSEE
FOR THE THIRTIETH JUDICIAL CIRCUIT AT MEMPHIS**

ACUMENT GLOBAL TECHNOLOGIES, INC.,

Plaintiff,

v.

MALLINCKRODT ARD, INC., et al.,

Defendants.

Docket No. CT-2275-19

CITY OF WASHINGTON

DISTRICT OF COLUMBIA

AFFIDAVIT OF BRIAN H. ROWE

Before me, the undersigned, personally appeared Brian H. Rowe, who after being duly sworn makes oath and states as follows:

1. My full name is Brian Hunt Rowe. My residence address 1010 8th ST NE, Unit 2, Washington DC, 20002. I am an attorney with Quinn Emanuel Urquhart & Sullivan, LLP, located at 1300 I St NW, Suite 900, Washington, D.C. 20005. My e-mail address is brianrowe@quinnemanuel.com and my telephone number is 202-538-8256.

2. I seek to represent Defendants Express Scripts Holding Company; Express Scripts, Inc.; CuraScript, Inc., doing business as CuraScript SD; Priority Healthcare Corp. and Priority Healthcare Distribution Inc., doing business as CuraScript SD; Accredo Health Group, Inc.; and United BioSource LLC (collectively the "Express Scripts Defendants") in the above-captioned action.

3. I am licensed to practice law in the District of Columbia, admission date October 17, 2016, registration number 1034974 and the state of Illinois, admission date November 4, 2010, registration number 6302889.

4. I am additionally licensed to practice before the Northern District Court of Illinois, admission date July 12, 2011; the Central District of Illinois, admission date February 11, 2014; and the District of Colorado, admission date March 24, 2015.

5. I am in good standing in both the District of Columbia and Illinois. Certificates of Good Standing from the District of Columbia and Illinois are attached as Exhibits A and B to this Affidavit and incorporated herein.

6. I have not been previously admitted *pro hac vice* in any trial or appellate court of Tennessee.

7. I have never been denied admission *pro hac vice*, nor have I had an admission *pro hac vice* revoked by any court in any jurisdiction.

8. I have never been disciplined or sanctioned by the Board of Professional Responsibility of the Supreme Court of Tennessee, by any similar lawyer disciplinary agency in any jurisdiction, or by any similar lawyer disciplinary authority.

9. There are no disciplinary actions or investigations concerning my conduct as a lawyer pending before the Board of Professional Responsibility of the Supreme Court of Tennessee, before any similar lawyer disciplinary agency in any jurisdiction, or before any similar lawyer disciplinary authority.

10. I am familiar with the Tennessee Rules of Professional Conduct and the rules governing the proceedings of the Circuit Court of Shelby County, Tennessee.


11. I consent to the disciplinary jurisdiction of the Board of Professional Responsibility of the Supreme Court of Tennessee and the courts of Tennessee in any matter arising out of the my conduct as a lawyer in the above-captioned action. I agree to be bound by the Tennessee Rules of Professional Conduct and any other rules of conduct applicable to lawyers generally admitted in Tennessee.

12. I am associated with Nathan Bicks (#10903), of the law firm Burch, Porter & Johnson, PLLC located at 130 North Court Avenue Memphis, TN 31803. Mr. Bicks's telephone number is (901) 524-5000.

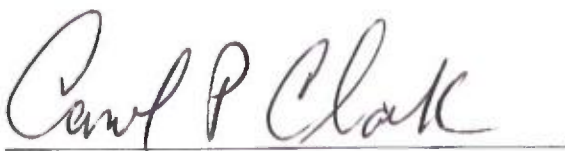
13. I have paid all fees required by this Rule in connection with the Motion for Admission.

14. Service of the *pro hac vice* motion and all associated papers will be made upon all counsel of record in the proceeding and upon the Board of Professional Responsibility of the Supreme Court of Tennessee.

I declare under penalty of perjury that the foregoing is true and correct.


Pro Hac Vice Applicant

Sworn to and subscribed before me this 10 day of October, 2019.


Notary Public

My commission expires: CAROL P. CLARK
NOTARY PUBLIC DISTRICT OF COLUMBIA
My Commission Expires March 31, 2021



EXHIBIT A



On behalf of JULIO A. CASTILLO, Clerk of the District of Columbia Court of Appeals,
the District of Columbia Bar does hereby certify that


Brian H Rowe

was duly qualified and admitted on October 17, 2016 as an attorney and counselor entitled to
practice before this Court; and is, on the date indicated below, an Active member in good
standing of this Bar.

**In Testimony Whereof,
I have hereunto subscribed my
name and affixed the seal of this
Court at the City of
Washington, D.C., on
September 30, 2019.**

A handwritten signature in black ink, which appears to read "Julio A. Castillo".

**JULIO A. CASTILLO
Clerk of the Court**

Issued By: 
District of Columbia Bar Membership

For questions or concerns, please contact the D.C. Bar Membership Office at 202-626-3475 or email
memberservices@dcbar.org.

EXHIBIT B

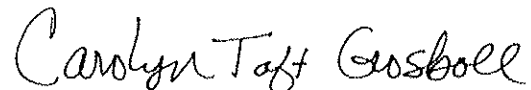
Certificate of Admission To the Bar of Illinois

I, Carolyn Taft Grosboll, Clerk of the Supreme Court of Illinois, do hereby certify that

Brian Hunt Rowe

has been duly licensed and admitted to practice as an Attorney and Counselor at Law within this State; has duly taken the required oath to support the CONSTITUTION OF THE UNITED STATES and of the STATE OF ILLINOIS, and also the oath of office prescribed by law, that said name was entered upon the Roll of Attorneys and Counselors in my office on 11/04/2010 and is in good standing, so far as the records of this office disclose.

IN WITNESS WHEREOF, I have hereunto
subscribed my name and affixed the
seal of said Court, this 3rd day of
October, 2019.



Clerk,
Supreme Court of the State of Illinois

**IN THE CIRCUIT COURT OF SHELBY COUNTY, TENNESSEE
FOR THE THIRTIETH JUDICIAL DISTRICT AT MEMPHIS**

ACUMENT GLOBAL TECHNOLOGIES, INC ,


Plaintiff,

v.

Cause No. CT-2275-19 Div. VII
NOTICE OF ENTRY REQUESTED

MALLINCKRODT ARD, INC., Formally
known as QUESTCOR PHARMACEUTICALS,
INC., MALLINCKRODT PLC, EXPRESS
SCRIPTS HOLDING COMPANY, EXPRESS
SCRIPTS, INC , CURAScript, INC d/b/a
CURAScript, SD, PRIORITY HEALTHCARE
CORP. AND PRIORITY HEALTHCARE
DISTRIBUTION, INC., d/b/a CURAScript
SD AND CURAScript SPECIALTY
DISTRIBUTION SD, respectively, ACCREDO
HEALTH GROUP, INC., UNITED BIOSOURCE
CORPORATION, and JAMES A. TUMLIN, M D.,

Defendants

FILED
JAN 09 2020
Circuit Court Clerk
BY  D.C.

**ORDER ON DEFENDANTS' MOTIONS FOR LEAVE TO FILE A RESPONSE TO
PLAINTIFF'S SURREPLY IN FURTHER SUPPORT OF THE DEFENDANTS'
MOTIONS TO DISMISS**

THIS matter is before the Court on the Defendants', Express Scripts, Inc. ("ESI"), CuraScript, Inc. ("CuraScript"), Priority Healthcare Corp., Priority Healthcare Distribution, Inc. d/b/a CuraScript SD ("CuraScript SD"), Accredo Health Group, Inc. ("Accredo") and United BioSource Corp. ("UBC") (collectively, the "Express Scripts Defendants"), and Mallinckrodt ARD, Inc and Mallinckrodt plc. (collectively the "Millinckrodt Defendants"), respective Motions for Leave to File a Response to Plaintiff's Surreply in Further Support of the Defendants' Motions to Dismiss, and upon the Plaintiff's Omnibus Response in Opposition, upon the arguments of counsel, the record as a whole and for good cause shown it is therefore:

**IN THE CIRCUIT COURT OF SHELBY COUNTY, TENNESSEE
FOR THE THIRTIETH JUDICIAL CIRCUIT AT MEMPHIS**

**ACUMENT GLOBAL TECHNOLOGIES,
INC.,**

Plaintiff,

v.

MALLINCKRODT ARD, INC., *et al.*,

Defendants.

DOCKET NO. CT-2275-19

DIVISION:

JURY TRIAL DEMANDED

**PLAINTIFF’S MEMORANDUM IN RESPONSE TO COURT’S INQUIRY
AS TO IMPLICATIONS OF RULE 54 ON ITS JURISDICTION**

Plaintiff Acument Global Technologies, Inc. (“Plaintiff” or “Acument”), by and through its undersigned counsel, hereby submits this memorandum to address this Court’s inquiry as to the potential implications, if any, of Rule 54 on this Court’s exercise of jurisdiction over this case, in relation to the pending Defendants’ Motions to Dismiss.¹

DISCUSSION

At a recent teleconference called for by the Court, the Court inquired of counsel for the parties as to the implications, if any, of Federal Rule 54 on the exercise of its jurisdiction over this case in wake of Plaintiff’s voluntary dismissal of its case from federal court as of right pursuant to Federal Rule 41(a). Because the Court did not wish to hear any additional argument

¹ It is not entirely clear to Plaintiff counsel the Court’s concern over its jurisdiction, given the clarity of Federal Rule 41(a) as to the implications of a notice of dismissal without prejudice. But, the lack of clear precedent in the federal courts addressing the Court’s concern about the potential implications of Rule 54 does not present grounds to deny jurisdiction, as it would deny Acument the right to sue in this Court, which is unquestioned and unquestionable. Further, because Plaintiff is having to respond to the Court’s question in a vacuum without knowing the Defendants’ position, Plaintiff reserves the right to seek to respond to the Defendants’ filing.

as to Mallinckrodt's claim that the Court is somehow estopped from proceeding because of the federal court ruling on its Motion to Dismiss, none will be presented in this Memorandum.²

Question presented: Does Federal Rule 54(b) impede this Court's exercise of jurisdiction over the *Acument* case, given that there remains a case pending in the Northern District of Illinois on behalf of the City of Rockford, another party, against some but not all of the same defendants sued here?

Answer: No.

The simple answer to the Court's question is that the federal court's Order presumptively operated as a determination under Rule 54(b), determining the finality of the *Acument* action alone in the *Rockford* Court. The case was dismissed, without prejudice. And because the *Rockford* Court's Order was a final "judgment", jurisdiction was relinquished. This Court thus has exclusive jurisdiction over the *Acument* case going forward.

Rule 41(a)(1)(A)(i)

The starting point for the Court's analysis must be Rule 41(a), which is the Rule by which the Plaintiff *Acument* dismissed its prior case from federal court. Rule 41(a)(1)(A)(i) provides that "the plaintiff may dismiss an action without a court order by filing . . . a notice of dismissal before the opposing party serves either an answer or a motion for summary judgment." "Unless the notice or stipulation states otherwise, the dismissal is without prejudice." Fed. R. Civ. P. 41(a)(1)(B).

² Plaintiff has presented unconverted legal precedent that Plaintiff's notice of dismissal under Rule 41(a) had the legal effect of nullifying any prior rulings of the federal court by which the Defendants seek an estoppel, because the notice of dismissal established, by rule, that the *Acument* case was never been brought in federal court. *E.g., Harrell v. Biomet Orthopedics, LLC*, 2015 U.S. Dist. LEXIS 179847 at * 16 (W.D.Tenn. 2015)(quoting *Dearth v. Mukasey*, 516 F.3d 413, 415 (6th Cir. 2008)).

It is undisputed that Acument exercised its right under Federal Rule 41(a)(1)(A)(i) in filing a notice of dismissal in the Northern District of Illinois. *See City of Rockford v. Mallinckrodt ARD, Inc., et. al.*, Case No. 17-cv-50107 (N.D.Ill., Western Div.)(“*Rockford*”) at ECF No. 195 (dismissing Acument’s action alone without prejudice). It is also undisputed the Notice of Voluntary Dismissal stated the dismissal was *without prejudice*. It is further undisputed that this filing took place before any opposing party served an answer or motion for summary judgment in the case. Finally, it is undisputed that the *Rockford* Court entered an Order, affirming that the Acument dismissal was without prejudice. *Rockford* ECF No. 201.

Thus, once the Notice of Voluntary Dismissal was filed, it was if the Acument case had never be brought. Although the *Rockford* Court chose to enter an Order dismissing the case without prejudice, the same was neither required nor warranted.³ There was no need for the Court to enter a “final judgment” in the Acument “action” under Rule 54(b). However, as discussed more fully below, because the *Rockford* Court chose to enter such Order, after giving the Defendants ample time to object, the Court’s Order operates as a “final judgment as to one or more, but fewer than all, ...parties” under Rule 54(b) because the Court impliedly “determine[d] that there was no just reason for delay.” Fed.R.Civ.Proc. 54(b). Accordingly, Plaintiff submits that the Court’s Order, while unnecessary for Acument to have taken a voluntary dismissal without prejudice under Rule 41(a), made clear to the Defendants – who chose not to object,⁴

³ "The notice of dismissal is self-effectuating and terminates the case in and of itself; no order or other action of the district court is required." *In re Amerijet Int'l, Inc.*, 785 F.3d 967, 973 (5th Cir. 2015) (per curiam). The *Rockford* Court’s prior Order on Defendants’ Rule 12 motions does not change the effect of the timely dismissal prior to answers being filed. *See, e.g., Swedberg v. Marotzke*, 339 F.3d 1139 (9th Cir. 2003)(citing cases).

⁴ The *Rockford* Court’s Order expressly acknowledged that “Defendants did not file an objection by the deadline stated in the court’s order taking Acument’s notice under advisement.

seek conditions on the dismissal,⁵ or otherwise respond⁶ – and this Court, that Acument’s dismissal was without prejudice to any future filing in any court, including this Court.

Starting with Rule 41(a), the analysis leads to this conclusion.

Rule 41(a)(1) is the shortest and surest route to abort a complaint when it is applicable. So long as plaintiff has not been served with his adversary's answer or motion for summary judgment he need do no more than file a notice of dismissal with the Clerk. That document itself closes the file. There is nothing the defendant can do to fan the ashes of that action into life and the court has no role to play. This is a matter of right running to the plaintiff and may not be extinguished or circumscribed by adversary or court. There is not even a perfunctory order of court closing the file. Its alpha and omega was the doing of the plaintiff alone. He suffers no impairment beyond his fee for filing.

Am. Cyanamid Co. v. McGhee, 317 F.2d 295, 297 (5th Cir. 1963); *see also Amerijet*, 785 F.3d at 973 (affirming *Am. Cyanamid*).

By its very title, Rule 41 also involves the dismissal of “actions”. To effectuate a “voluntary dismissal”, the plaintiff may do so only as to “an action”. Fed.R.Civ.Proc. 41(a)(1)(A). The effect of such dismiss is “without prejudice”, whether expressly stated or not. Fed.R.Civ.Proc. 41(a)(1)(B); *see also, Marshall v. Kan. City S. Ry. Co*, 378 F.3d 495, 501 (5th Cir. 2004)(where a dismissal under Rule 41(a) is silent, it is presumed to be without prejudice).

Rule 54(b)

Accordingly, there being no objection, Acument is terminated from this case. *Rockford* ECF No. 201.

⁵ It would have been error for the *Rockford* Court to have conditioned any re-filing of the Acument Complaint in the Northern District of Illinois. *See, e.g., Bechuck v. Home Depot U.S.A., Inc.*, 814 F.3d 287 (5th Cir. 2016)(district court erred in attaching refiling restriction on case dismissed under Rule 41(a) as to only one of two defendants). There is no “judicial function” under Rule 41(a)(1) as with Rule 41(a)(2). *See American Cyanamid Co. v. McGhee*, 317 F.2d 295, 298 (5th Cir. 1963); *see also, D.C. Elecs., Inc. v. Narton Corp.*, 511 F.2d 294 (6th Cir. 1975).

⁶ The Defendants also could not seek to have the *Rockford* Court turn its prior dismissal without prejudice, into a dismissal with prejudice, simply because Acument exercised its right under Rule 41(a). The case of *In re Bath & Kitchen Fixtures Antitrust Litigation* makes this abundantly clear.

In view of the unambiguous precedent involving the application of Rule 41(a), the question arises as to whether an order of the *Rockford* Court was required under Rule 54(b) in order to relinquish jurisdiction over the Acument case, even though jurisdiction was retained over the City of Rockford case. Plaintiff has found no clear answer in the case law. However, in the context of appellate jurisdiction, there is ample discussion of the “finality trap”, whereby a party use a dismissal without prejudice under Rule 41 to create a final, appealable judgment. *See, e.g., Williams v. Taylor Seidenbach, Inc.*, 935 F.3d 358, 360 (5th Cir. 2019). But, even in these cases, in distinguishing the “finality” of a case for purposes of appeal, the courts have observed that a dismissal under Rule 41(a) means that the case dismissed is “no longer [] pending in the district court and no further proceedings in the action are proper.” *Id.* (citing authorities). The cases state that a “subsequent Rule 54(b) judgment could have no effect.” *Id.* In other words, what the *Rockford* Court did in the case of Acument is enter an Order, upon asking for but receiving no objection from the Defendants, affirming that the Rule 41(a) dismissal was without prejudice and that the Court’s jurisdiction over the Acument case was relinquished.

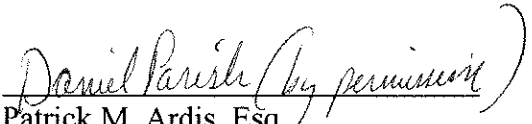
CONCLUSION

For the foregoing reasons, and those stated in Plaintiff’s prior opposition papers and at the hearing on Defendants’ Motions to Dismiss, this Court has jurisdiction over this case by which to deny the Defendants’ pending Motions to Dismiss and go forward.

Respectfully submitted,

Dated: January 10, 2020

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing has been delivered via U.S. mail and electronic mail this 10th day of January, 2020.

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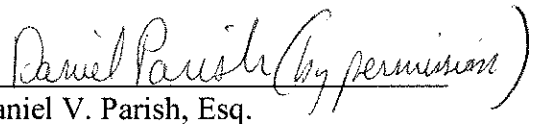
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**IN THE CIRCUIT COURT OF SHELBY COUNTY, TENNESSEE
FOR THE THIRTIETH JUDICIAL DISTRICT AT MEMPHIS**

ACUMENT GLOBAL TECHNOLOGIES, INC ,

Plaintiff,

v.

Cause No CT-2275-19 Div. VII
NOTICE OF ENTRY REQUESTED

MALLINCKRODT ARD, INC., Formally
known as QUESTCOR PHARMACEUTICALS,
INC., MALLINCKRODT PLC, EXPRESS
SCRIPTS HOLDING COMPANY, EXPRESS
SCRIPTS, INC , CURASCRIPT, INC d/b/a
CURASCRIPT, SD, PRIORITY HEALTHCARE
CORP. AND PRIORITY HEALTHCARE
DISTRIBUTION, INC , d/b/a CURASCRIPT
SD AND CURASCRIPT SPECIALTY
DISTRIBUTION SD, respectively, ACCREDO
HEALTH GROUP, INC , UNITED BIOSOURCE
CORPORATION, and JAMES A TUMLIN, M D ,

Defendants

FILED
JAN 14 2020
CIRCUIT COURT CLERK
BY [Signature] D.C.

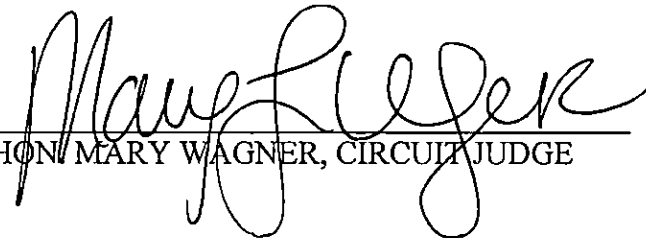
**ORDER ON DEFENDANTS' MOTIONS FOR LEAVE TO FILE A RESPONSE TO
PLAINTIFF'S SURREPLY IN FURTHER SUPPORT OF THE DEFENDANTS'
MOTIONS TO DISMISS**

THIS matter is before the Court on the Defendants', Express Scripts, Inc. ("ESI"), CuraScript, Inc. ("CuraScript"), Priority Healthcare Corp., Priority Healthcare Distribution, Inc. d/b/a CuraScript SD ("CuraScript SD"), Accredo Health Group, Inc. ("Accredo") and United BioSource Corp. ("UBC") (collectively, the "Express Scripts Defendants"), and Mallinckrodt ARD, Inc and Mallinckrodt plc (collectively the "Mallinckrodt Defendants"), respective Motions for Leave to File a Response to Plaintiff's Sur-reply in Further Support of the Defendants' Motions to Dismiss, and upon the Plaintiff's Omnibus Response in Opposition, upon the arguments of counsel, the record as a whole and for good cause shown it is therefore

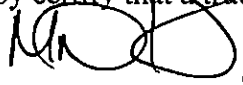
ORDERED, DECREED and ADJUDGED that the Defendants' above referenced

Motions for Leave to File a Response shall be and are DENIED.

ENTERED this the 14 day of January 2020 *nunc pro tunc* to January 9,
2020.¹


HON. MARY WAGNER, CIRCUIT JUDGE

CERTIFICATE OF SERVICE:

I Hereby certify that a true and accurate copy of the foregoing was sent to the following via U S
Mail  Clerk 1/14/2020.

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Attorneys for Acument Global Technologies, Inc

¹ This Order is entered nunc pro tunc to January 9, 2020 as the Court originally entered this Order on that date, with signatures by all of the counsel of record (some as to form only), but the Order was misplaced by the Clerk's office

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